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US006071305A

United States Patent [19]

Brown et al.

[11] Patent Number: 6,071,305

[45] Date of Patent: Jun. 6, 2000

[54] **DIRECTIONAL DRUG DELIVERY STENT AND METHOD OF USE**

[75] Inventors: **James E. Brown**, Los Gatos; **Wouter E. Roorda**, Newark, both of Calif.

[73] Assignee: **Alza Corporation**, Del.

[21] Appl. No.: **08/976,725**

[22] Filed: **Nov. 24, 1997**

Related U.S. Application Data

[60] Provisional application No. 60/031,471, Nov. 25, 1996.

[51] **Int. Cl.**[7] **A61F 2/06**

[52] **U.S. Cl.** **623/1**; 623/12; 606/198; 606/191

[58] **Field of Search** 623/1, 12; 604/891.1, 604/892.1; 606/198, 191

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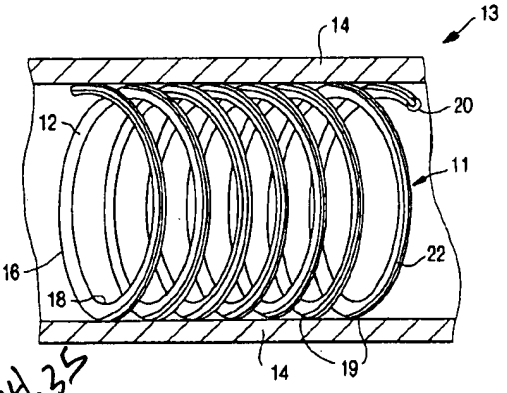
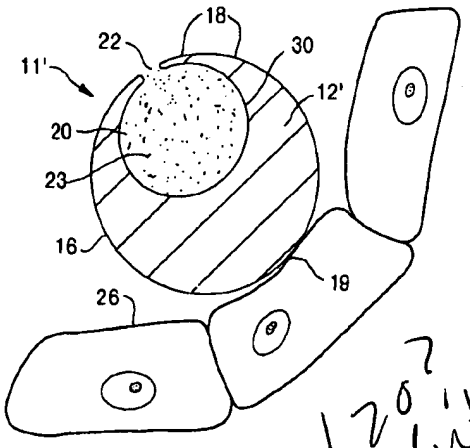
Primary Examiner—David H. Willse
Assistant Examiner—Suzette J. Jackson
Attorney, Agent, or Firm—Burns, Doane, Swecker & Mathis, L.L.P.

[57] **ABSTRACT**

The invention relates to a directional drug delivery stent which includes an elongated or tubular member having a cavity containing a biologically active agent. In one embodiment, the active agent is diffused from the reservoir directly to the walls of a body lumen, such as a blood vessel, through directional delivery openings arranged on an outer surface of the elongated member. Another variation of the stent includes an osmotic engine assembly for controlling the delivery of the active agent from the reservoir. The drugs which may be applied by the directional delivery stent include, but are not limited to, steroids, anti-inflammatory agents, restenosis preventing drugs, anti-thrombotic drugs, and tissue growth regulating drugs. The invention also relates to a method of using the directional drug delivery stent.

21 Claims, 8 Drawing Sheets





US006537202B1

(12) **United States Patent**
Frantzen

(10) **Patent No.: US 6,537,202 B1**
(45) **Date of Patent: Mar. 25, 2003**

(54) **METHOD FOR POLISHING SURGICAL STENTS**

(75) Inventor: **John J. Frantzen**, Copperopolis, CA (US)

(73) Assignee: **Cook Incorporated**, Bloomington, IN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 420 days.

(21) Appl. No.: **09/072,605**

(22) Filed: **May 5, 1998**

Related U.S. Application Data

(63) Continuation of application No. 08/870,962, filed on Jun. 6, 1997, now Pat. No. 5,746,691.

(51) **Int. Cl.**[7] **A61F 2/04**; A61F 2/06

(52) **U.S. Cl.** **600/36**; 623/1.15; 623/921; 451/36

(58) **Field of Search** 451/36, 104, 113, 451/40, 89; 623/1, 12, 901, 1.15, 23.7, 920, 921; 606/198; 600/36

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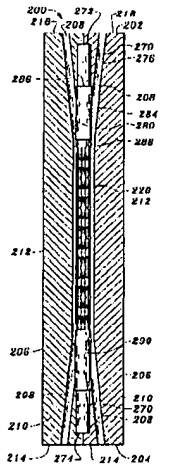
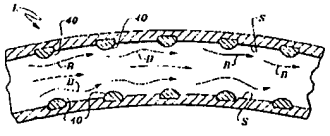
Primary Examiner—Paul Prebilic
(74) *Attorney, Agent, or Firm*—Richard J. Godlewski

(57) **ABSTRACT**

A method for polishing radially expandable surgical stents is disclosed where fluid abrasive media M flows over surfaces of the stent **10** causing the surfaces of the stent **10** to be polished and streamlined. The stent **10** is temporarily provided with cylindrical support ends **20**, which are not radially expandable to support the stent **10** during the polishing process. An interior polishing fixture **100** is provided which has cylindrical chambers **135** therein adapted to receive a stent **10** therein. Fluid abrasive media M then flows into bores **108** in the fixture **100** leading to the cylindrical chambers **135** and adjacent the inner diameter surfaces of the stent **10**. Surfaces of the stent **10** forming the outer diameter are polished by placing the stent **10** within an exterior polishing fixture **200** which has a cylindrical recess **220** therein. The cylindrical recess **220** has a diameter greater than a diameter of outer surfaces of the stent **10** and includes a cylindrical shaft **270** passing axially through the cylindrical recess **220** upon which the stent **10** is located. Slanted bores **208** pass through walls of the exterior polishing fixture **200** and into the cylindrical recess **220**, directing the abrasive media M adjacent exterior surfaces of the stent **10** and causing polishing of the exterior surfaces of the stent **10**. The direction of abrasive media M flow can be reversed to make streamlining of segments of the stent **10** occur in a symmetrical fashion. After polishing of the stent **10** is completed, the cylindrical support ends **20** are removed and the stent **10** is ready for implantation and radial expansion within a body lumen L. When polished and streamlined, the radially expandable surgical stent **10** more effectively supports a body lumen L without excessive thrombus, restenosis and other medical complications.

5 Claims, 7 Drawing Sheets





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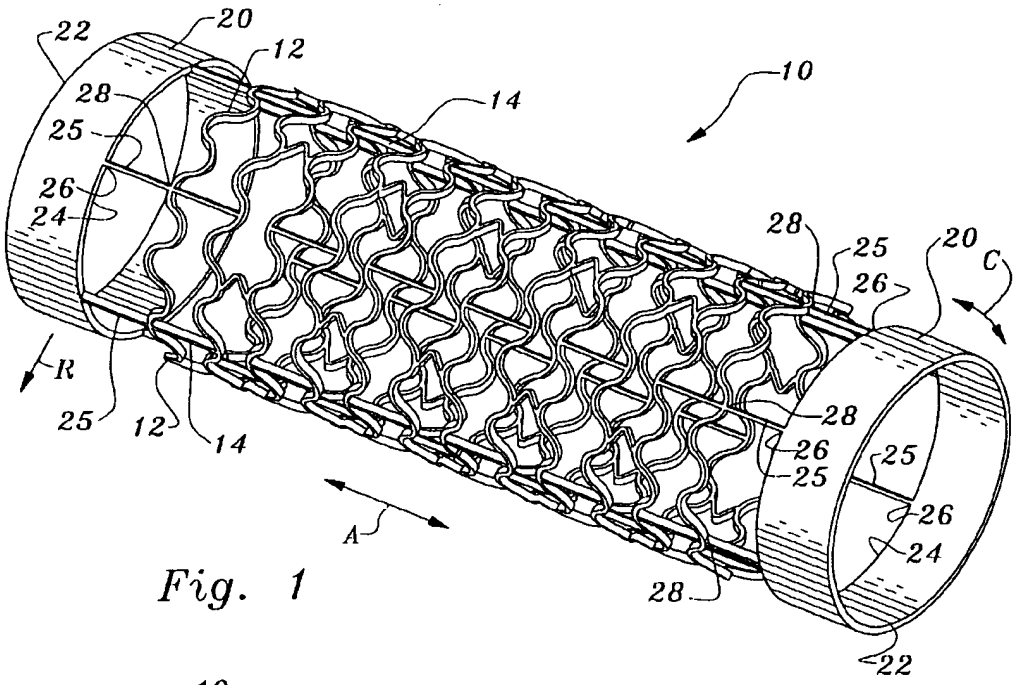
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Fig. 1

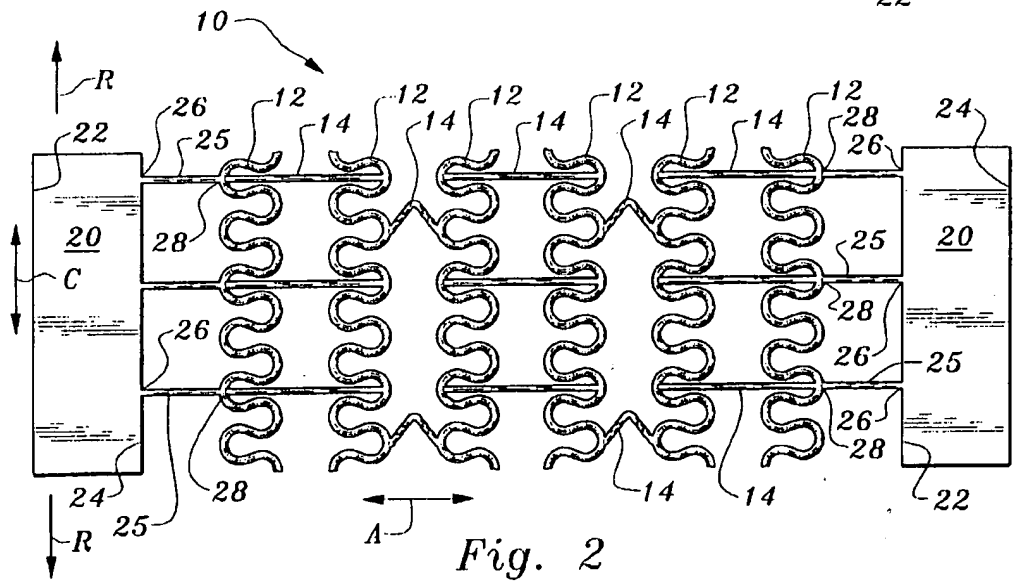
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Fig. 2

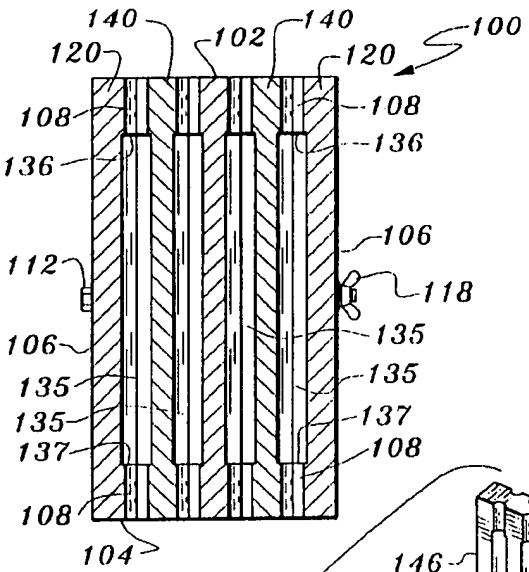

Fig. 4

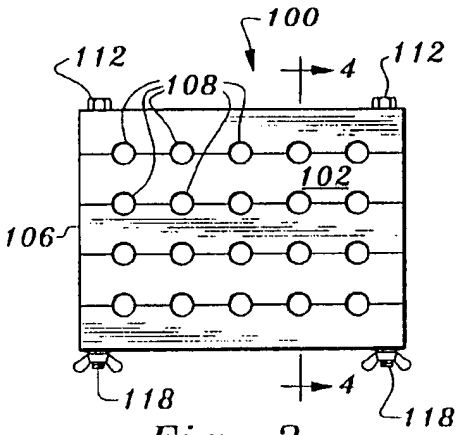

Fig. 3

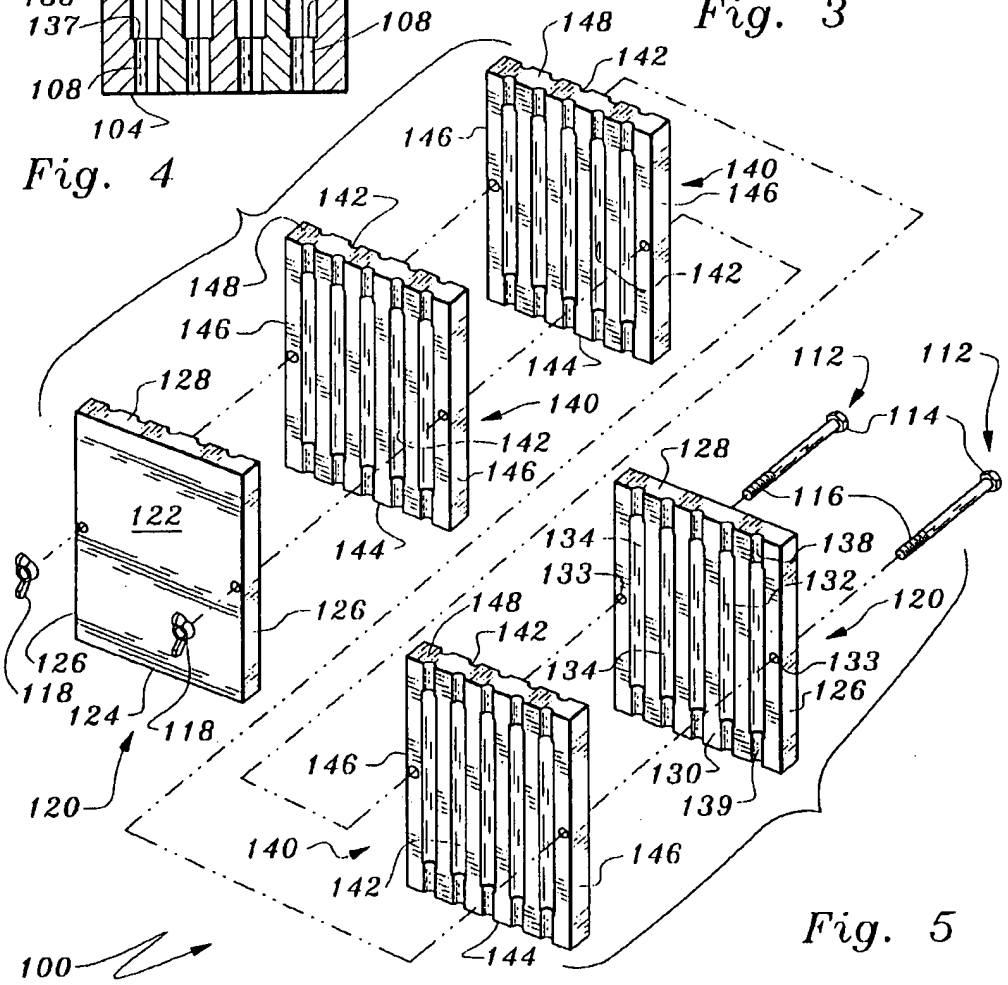

Fig. 5

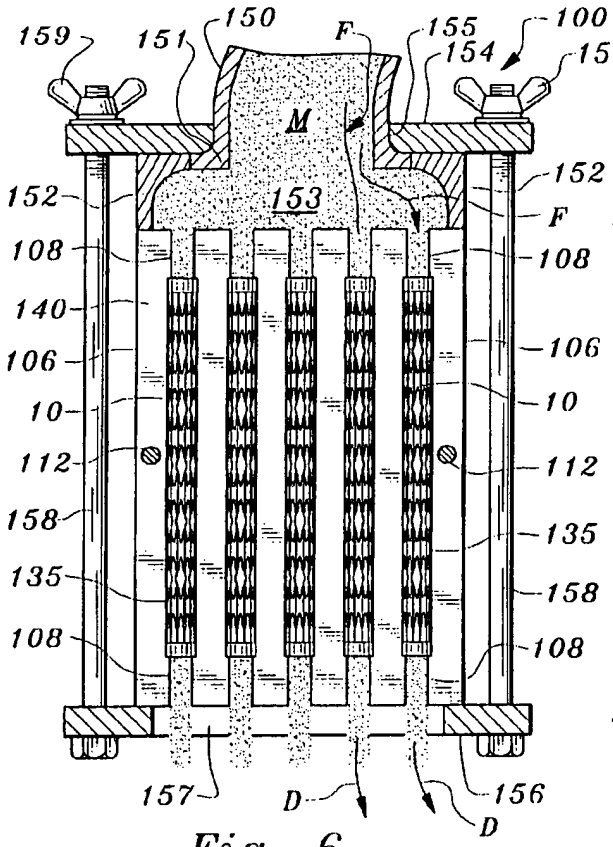

Fig. 6

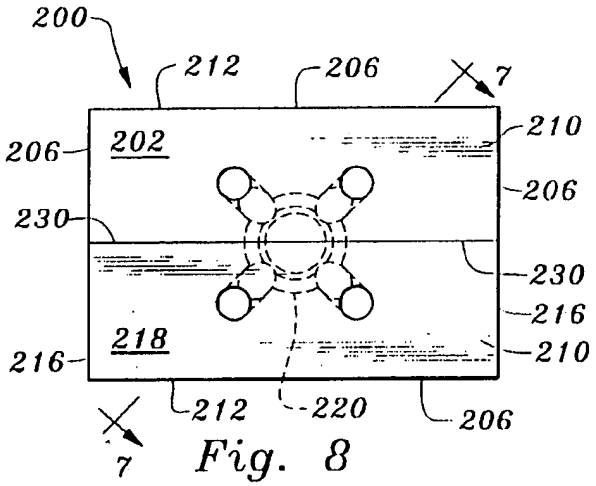

Fig. 8

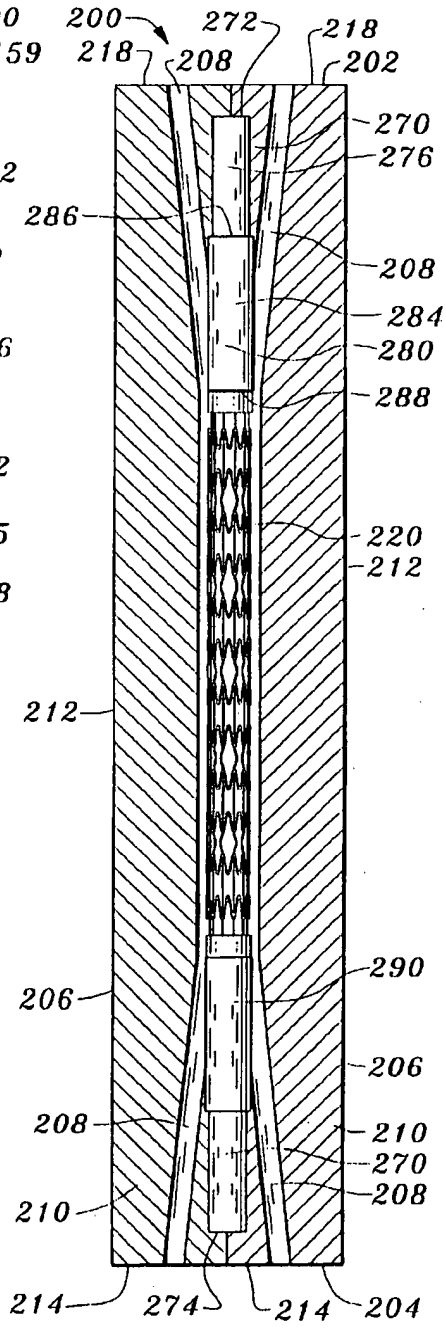

Fig. 7

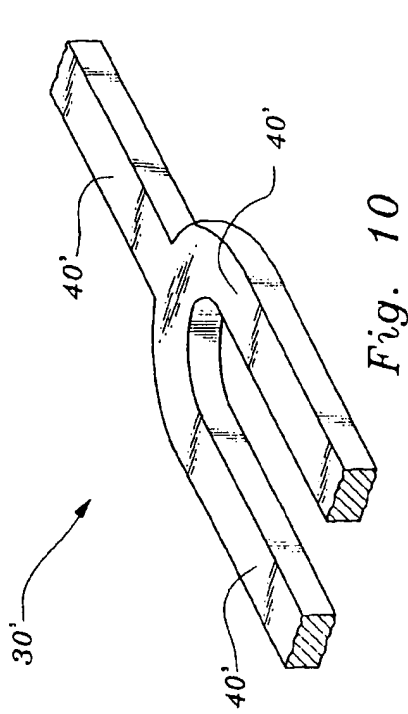

Fig. 10

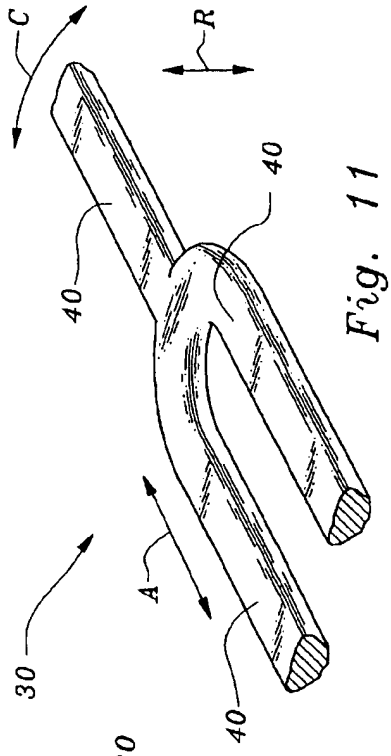

Fig. 11

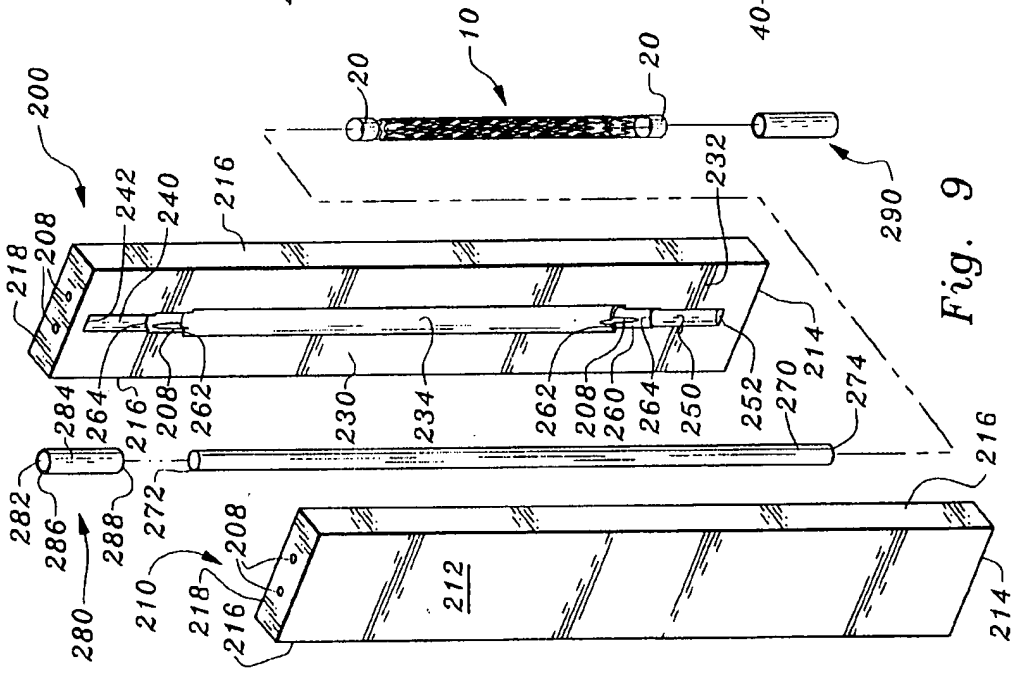

Fig. 9

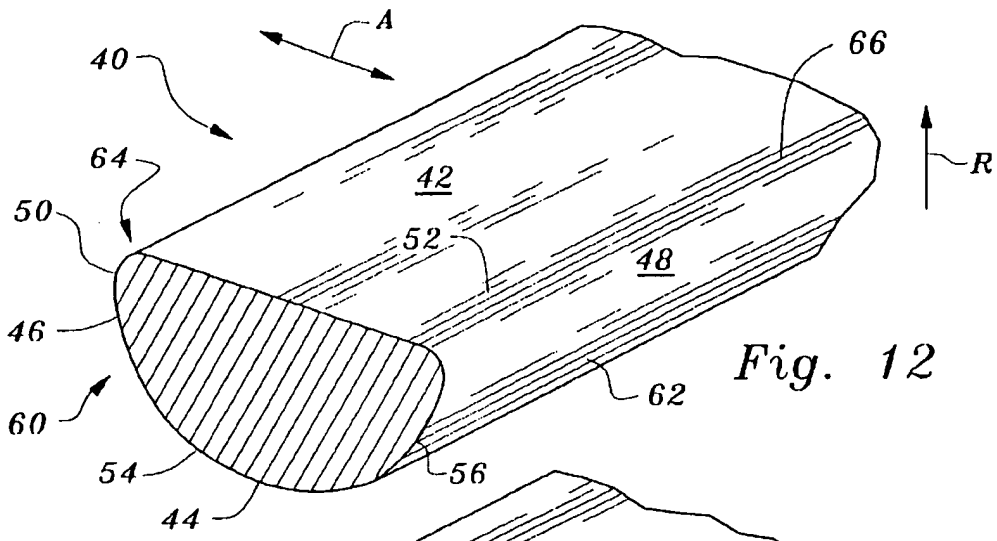

Fig. 12

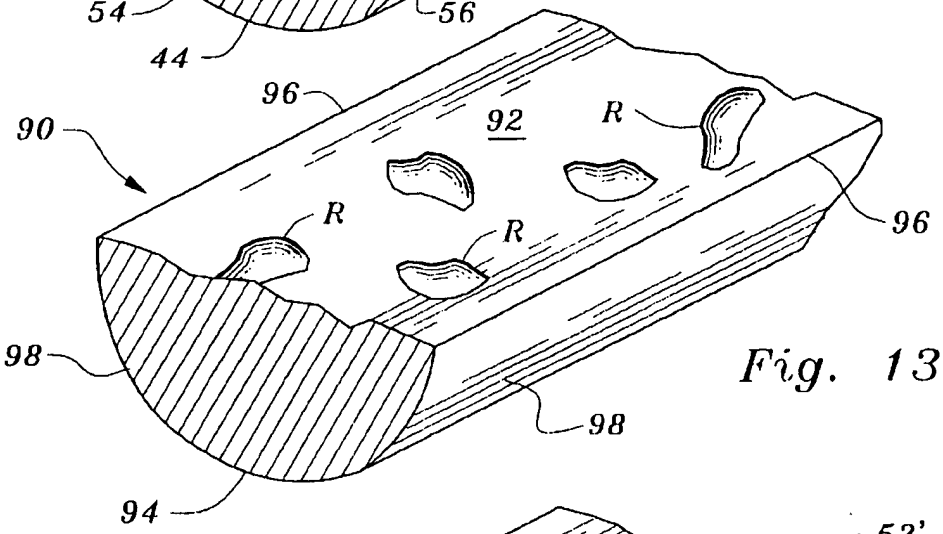

Fig. 13

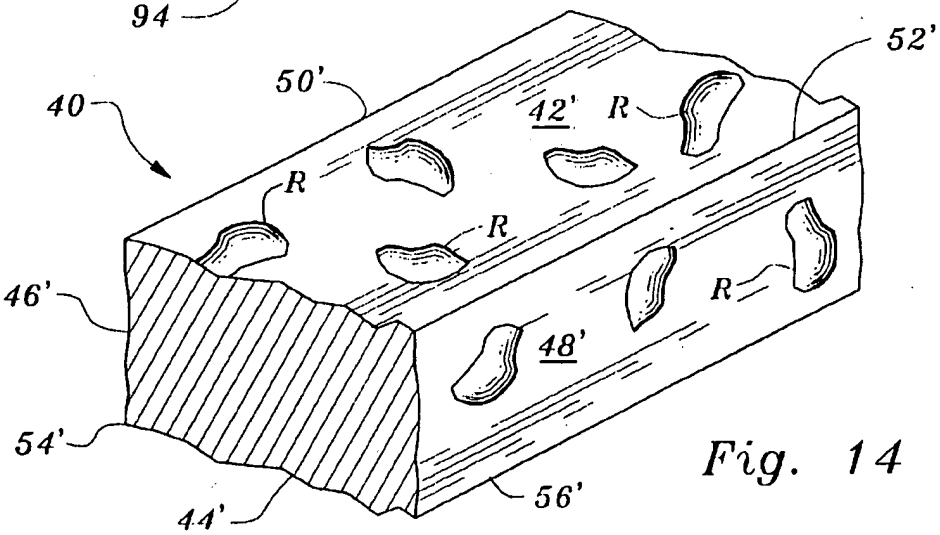

Fig. 14

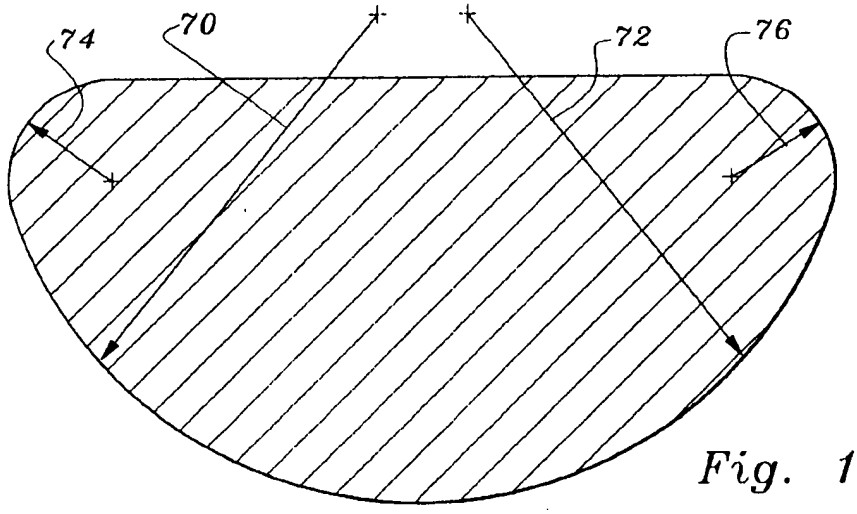

Fig. 15

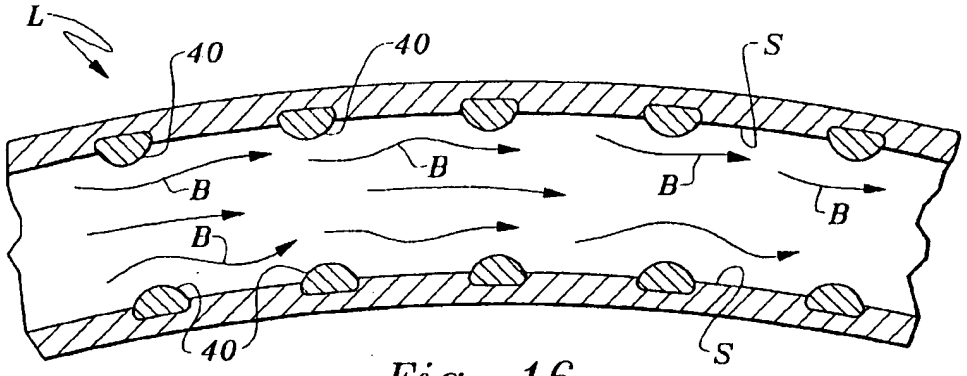

Fig. 16

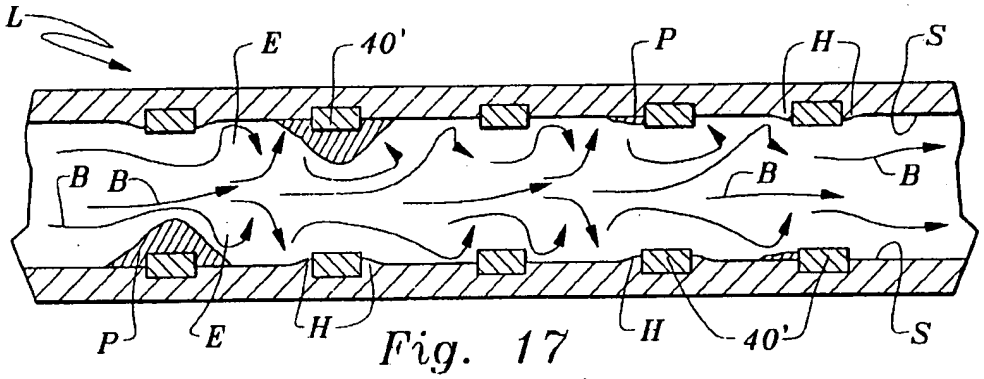

Fig. 17
(PRIOR ART)

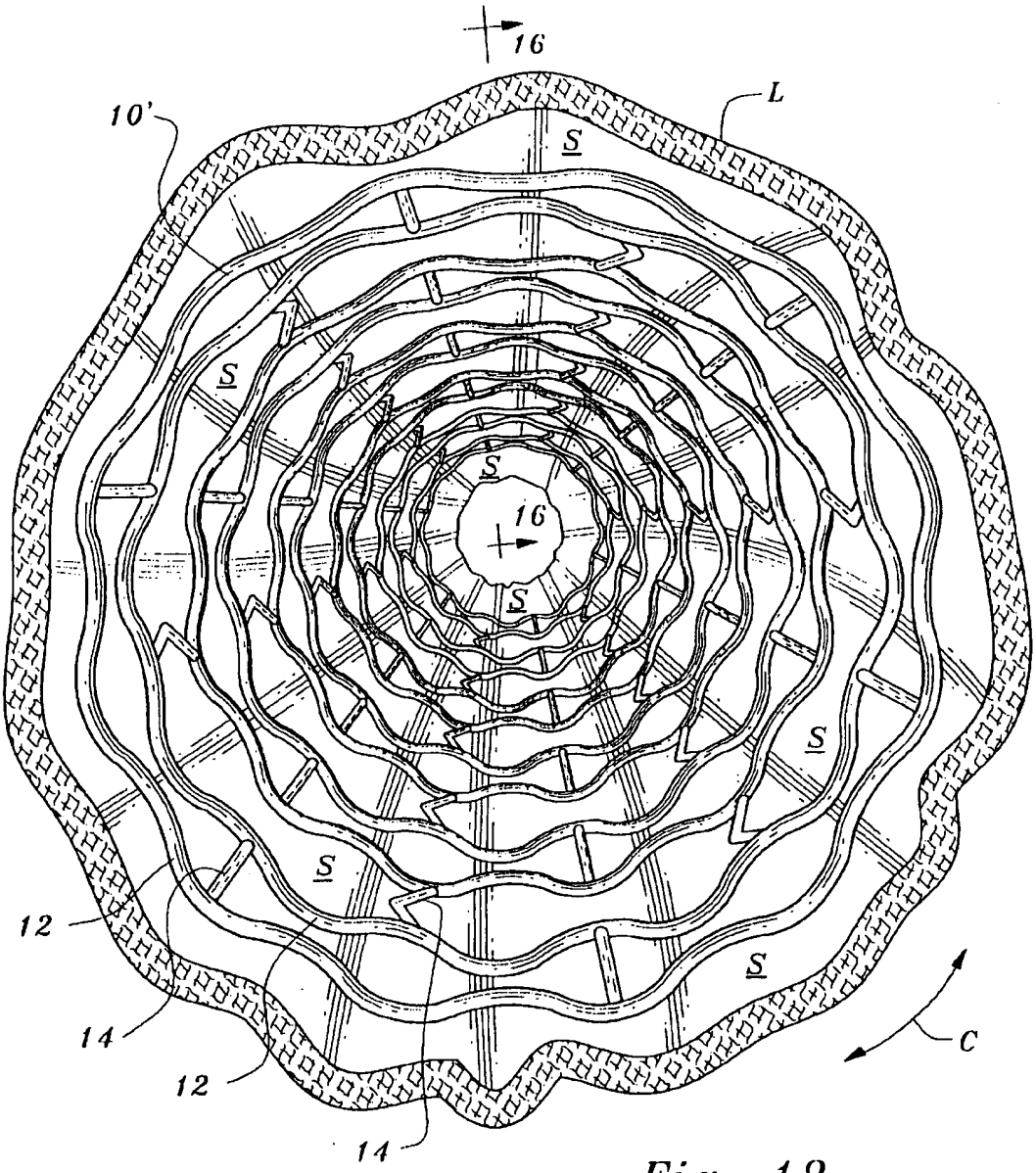

Fig. 18

METHOD FOR POLISHING SURGICAL STENTS

"This is a continuation of U.S. patent application Ser. No. 08/870,962 filed Jun. 6, 1997 now U.S. Pat. No. 5,746,691."

FIELD OF THE INVENTION

The following invention relates to the polishing of radially expandable surgical stents which can be surgically implanted into a body lumen, such as an artery, and be radially expanded to support the lumen. More specifically, this invention relates to fixtures used for supporting a radially expandable surgical stent while an abrasive media is flowed over surfaces of the stent to polish the stent and provide an inner surface of the stent with a streamlined contour, and methods for using such fixtures while polishing surgical stents.

BACKGROUND OF THE INVENTION

Surgical stents have long been known which can be surgically implanted into a body lumen, such as an artery, to reinforce, support, repair or otherwise enhance the performance of the lumen. For instance, in cardiovascular surgery it is often desirable to place a stent in the coronary artery at a location where the artery is damaged or is susceptible to collapse. The stent, once in place, reinforces that portion of the artery allowing normal blood flow to occur through the artery. One form of stent which is particularly desirable for implantation in arteries and other body lumens is a tubular stent which is formed as a complete tubular cylinder and can be radially expanded from a first smaller diameter to a second larger diameter. Such radially expandable stents can be inserted into the artery by being located on a catheter and fed internally through the arterial pathways of the patient until the unexpanded stent is located where desired. The catheter is fitted with a balloon or other expansion mechanism which exerts a radial pressure outward on the stent, causing the stent to expand radially to a larger diameter. Such expandable stents exhibit sufficient rigidity after being expanded that they will remain expanded after the catheter has been removed.

Radially expandable stents come in a variety of different configurations to provide optimal performance in various different particular circumstances. For instance, the patents to Lau (U.S. Pat. Nos. 5,514,154, 5,421,955, and 5,242,399), Baracci (U.S. Pat. No. 5,531,741), Gaterud (U.S. Pat. No. 5,522,882), Gianturco (U.S. Pat. Nos. 5,507,771 and 5,314,444), Termin (U.S. Pat. No. 5,496,277), Lane (U.S. Pat. No. 5,494,029), Maeda (U.S. Pat. No. 5,507,767), Marin (U.S. Pat. No. 5,443,477), Khosravi (U.S. Pat. No. 5,441,515), Jessen (U.S. Pat. No. 5,425,739), Hickle (U.S. Pat. No. 5,139,480), Schatz (U.S. Pat. No. 5,195,984), Fordenbacher (U.S. Pat. No. 5,549,662) and Wiktor (U.S. Pat. No. 5,133,732), each include some form of radially expandable stent for implantation into a body lumen.

Some problems which have been exhibited by prior art stents include that the inner and outer surfaces of the stents are not sufficiently streamlined or finely enough polished to prevent certain medical complications. For instance, thrombus, a phenomenon where a fibrous clot forms within cracks and other irregularities in the surface finish of an implanted object (such as a stent), is enhanced when the surfaces of the stent are not finely polished. Additionally, when the inner surface of the stent is substantially planar and has abrupt edges along borders thereof, turbulence is introduced into the blood. When a stent having such an abrupt edge is implanted into an artery, plaque and other deposits are provided with a site for collection and potential narrowing of the arteries and restriction of blood flow. This plaque buildup adjacent an implanted object (such as a stent) is referred to as "restenosis."

While many prior art stents do exhibit somewhat polished surfaces, they are typically not sufficiently finely polished, especially on tubular stents having smaller diameters, to prevent restenosis and thrombus adjacent the stent after the stent is implanted into the artery. Such prior art stents also lack a streamlined contour to minimize disruption of bodily fluid flow through the lumen and to further discourage restenosis surrounding the stent.

A primary reason why prior art stents fail to exhibit sufficiently finely polished surfaces to avoid the drawbacks discussed above is the lack of a polishing process which can effectively provide the finely polished surface desired, especially on stents having smaller inner diameters. Stents are typically polished in one of two processes, either chemical etching or electropolishing. With chemical etching, chemicals are used which react chemically with the material forming the stent, causing the material forming the stent to be driven into solution. Chemicals are selected which have a strength sufficient to cause rough areas of the stent to be dissolved, but not so strong that smooth areas of the stent are detrimentally altered. Chemical etching, while somewhat effective in removing gross irregularities from the surfaces of the stent, fail to adequately provide the desired finely polished surface.

Electropolishing typically involves providing an electrolytic solution, placing the stent within the electrolytic solution, placing a cathode within the solution and not contacting the stent and coupling an anode to the stent. When an electric voltage is provided between the anode and the cathode, the stent is caused to lose portions of its outer surface when the elements forming the stent are driven into solution and carried to the cathode for deposition upon the cathode. In essence, such electrolytic polishing is the reverse of commonly used electrical plating processes with material from the surface of the stent being removed rather than added to the stent. The rougher surfaces of the stent are more readily driven into solution and hence removed from the surfaces of the stent, smoothing the surfaces of the stent somewhat.

Because the surfaces of the stent forming the inner diameter of the stent benefit from a high degree of polishing, one known technique is to form the cathode as a thin wire passing along a central axis of the stent entirely through the stent from one end to the other, but without physically contacting the stent. When a voltage is provided between the cathode wire passing along the central axis of the stent and the stent itself, the inner surfaces of the stent are provided with the greatest electric field density and hence are the surfaces which are most polished during this process. While typically more effective than chemical etching, electrolytic polishing also fails to provide a sufficiently finely polished stent to significantly discourage thrombus and restenosis adjacent surfaces of the stent.

Accordingly, a need exists for a method and apparatus for polishing surfaces of a radially expandable surgical stent, and particularly the surfaces forming the inner diameter of the stent, with a sufficient degree of polish to reduce or eliminate the occurrence of thrombus and restenosis when surgical stents are implanted within a body lumen.

SUMMARY OF THE INVENTION

The radially expandable surgical stent which is polished and streamlined by the method and apparatus of this inven-

tion exhibits an overall tubular cylindrical hollow seamless contour which can feature any of a variety of different arrangements for individual elements and segments forming the stent. The various different segments of the stent have a generally elongate, substantially constant cross-sectional contour which can either be oriented to extend axially, circumferentially, or some combination thereof, with each segment located between an inner diameter of the stent and an outer diameter of the stent. Each segment includes an outer surface coextensive with the outer diameter of the stent and an inner surface coextensive with the inner diameter of the stent. Each segment also includes lateral surfaces extending between the inner surface and the outer surface which can either be a leading surface on an upstream side of the segment, a trailing surface on a downstream side of the segment, or a lateral surface generally aligned axially with the stent.

The inner surface of each segment of the stent is extensively streamlined by the polishing method and apparatus of this invention to minimize disruption of bodily fluid flow through the body lumen. Specifically, the inner surface includes an inner leading edge and an inner trailing edge bordering the inner surface. Each inner edge is defined by an inner curve having a relatively large radius of curvature when compared to the radii of curvature exhibited by outer edges adjacent the outer surface of each stent segment. Because the inner edges have a large radius of curvature, they do not present any abrupt transition in flow for bodily fluids passing over the inner surface of the stent segment, particularly when the stent segment is aligned circumferentially with bodily fluid flow passing adjacent the inner surface from a leading inner edge to a trailing inner edge.

The surfaces of each stent segment are honed and polished to have a surface finish which is free from abrupt transitions and irregularities, such as prominences extending more than five micro inches above adjacent portions of the surrounding surface. Smooth flow of blood or other bodily fluids over the surfaces of the stent can thus be preserved and a risk of medical complications such as restenosis and thrombus can be minimized.

The polishing apparatus of this invention includes a fixture which rigidly supports at least one radially expandable surgical stent within a cylindrical chamber in the fixture. A bore passes through the fixture and leads both into the cylindrical chamber and out of the cylindrical chamber. A source of fluid abrasive media is placed adjacent the fixture in an orientation which allows the fluid abrasive media to pass through the bores and into the cylindrical chamber. The cylindrical chamber has a diameter similar to the outer diameter of the stent so that the fluid abrasive media is forced to pass only through the interior of the stent and adjacent the surfaces forming the inner diameter of the stent. As the fluid abrasive media passes through the cylindrical chamber and adjacent the surfaces forming the inner diameter of the stent, the surfaces forming the inner diameter of the stent are polished to a level of smoothness determined by the particle size of the abrasive media, the amount of time which the abrasive media flows past the surfaces of the stent and other factors known in the honing arts.

When it is desired that the outer diameter of the stent be polished, a stent exterior polishing fixture is provided having a cylindrical recess located therein with slanted bores leading from a top and bottom of the fixture to the cylindrical recess. The cylindrical recess has a diameter greater than the diameter of the outer diameter of the stent. A shaft is located within the cylindrical recess with a central axis of the shaft aligned with a central axis of the cylindrical recess. The shaft has a diameter similar to the inner diameter of the stent. The stent is placed on the shaft and within the cylindrical recess so that abrasive media flowing through the slanted bores and into the cylindrical recess are precluded from flowing adjacent the surfaces forming the inner diameter of the stent, but rather flow adjacent surfaces forming the outer diameter of the stent for polishing of the outer diameter of the stent.

In utilizing the various fixtures for supporting the stent during this polishing process, the stent is preferably initially provided with, radially-non-expandable cylindrical support ends adjacent each end of the stent. These cylindrical support ends are located along with the stent within the cylindrical chamber or cylindrical recess of one of the fixtures and provide additional support for the stent during the polishing process. The support ends prevent collapse of the stent and excessive polishing of ends of the stent during the polishing process.

The polishing process can be additionally facilitated by ultrasonically vibrating the abrasive media and elevating the pressure of the abrasive media as it flows through the fixture and adjacent surfaces of the stent. If it is desired that the stent be provided with a streamlined contour which is not biased in any one direction, the stent can be removed and reoriented within the fixture for polishing in a reverse direction or the fixture can be disconnected from the source of abrasive media, rotated 180° and recoupled to the source of abrasive media for polishing in a reverse direction. Once the polishing process is completed, the cylindrical support ends are removed from the stent. The stent is then ready for implantation within a body lumen with such finely polished surfaces that restenosis and thrombus are minimized.

OBJECTS OF THE INVENTION

Accordingly, a primary object of the present invention is to provide a method for polishing surfaces of a radially expandable surgical stent which includes flowing a fluid abrasive media adjacent surfaces of the stent to be polished until the stent exhibits a desired finish.

Another object of the present invention is to provide a method for streamlining surfaces of a radially expandable surgical stent by flowing fluid abrasive media adjacent surfaces of the stent to be streamlined.

Another object of the present invention is to provide a method for polishing a radially expandable surgical stent which can polish multiple stents simultaneously.

Another object of the present invention is to provide a fixture for a radially expandable surgical stent polishing process which holds and supports the stent while fluid abrasive media is flowed adjacent surfaces of the stent and which can be easily loaded and unloaded with stents to be polished.

Another object of the present invention is to provide a fixture for a stent polishing process which restricts fluid abrasive media flow to the surfaces forming the inner diameter of the stent.

Another object of the present invention is to provide a fixture for a stent polishing process which restricts fluid abrasive media flow to the surfaces forming the outer diameter of the stent.

Another object of the present invention is to provide a stent polishing fixture which can be readily attached to honing equipment which uses elevated pressure fluid abrasive media and ultrasonic vibration of the fluid abrasive media and directs the fluid abrasive media through the fixture.

Another object of the present invention is to provide a surgical stent which minimizes medical complications such as restenosis and thrombus adjacent the stent.

Another object of the present invention is to provide a radially expandable surgical stent which has a finish smoothness which minimizes medical complications such as restenosis and thrombus adjacent the stent when the stent is implanted within an artery or other body lumen.

Another object of the present invention is to provide a surgical stent which can support a body lumen while minimizing disruption of flow of bodily fluids through the lumen.

Another object of the present invention is to provide a surgical stent which is reversible and can be implanted in two distinct orientations rotated 180° from each other without altering performance of the surgical stent.

Another object of the present invention is to provide a surgical stent which features an inner surface which has edges with greater radii of curvature than radii of curvature of outer edges bordering an outer surface of segments of the stent, such that disruption to blood flow within a body lumen in which the stent is implanted is minimized and the outer surface of the stent is securely held adjacent a wall of the lumen.

Other further objects of the present invention will become apparent from a careful reading of the included description and claims and from a review of the drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a radially expandable surgical stent with cylindrical support ends located adjacent each end of the stent, such that the stent is ready to be placed within a fixture for polishing of surfaces of the stent. The stent is shown with circumferential elements radially expanded to make surfaces of the stent more readily discernible. However, the circumferential elements of the stent would in fact be not radially expanded when attached to the cylindrical support ends.

FIG. **2** is a cylindrical projection of a portion of that which is shown in FIG. **1** with the circumferential elements shown not radially expanded as the circumferential elements would appear when attached to the cylindrical support ends and during the polishing process of this invention.

FIG. **3** is a top plan view of a stent interior surface polishing fixture for use according to the polishing method of this invention.

FIG. **4** is a full sectional view of that which is shown in FIG. **3** taken along lines **4**—**4** of FIG. **3**.

FIG. **5** is a perspective exploded parts view of that which is shown in FIG. **3** revealing how separate plates of the fixture are coupled together to form the fixture of FIG. **3**.

FIG. **6** is a sectional view of the fixture of FIG. **3** with other portions of the honing equipment and fluid abrasive media supply attached to the fixture and revealing how fluid abrasive media is caused to flow through the fixture and adjacent surfaces of the stent forming the inner diameter of the stent.

FIG. **7** is a full sectional view taken along lines **7**—**7** of FIG. **8** and revealing details of a polishing fixture for polishing exterior surfaces of a stent.

FIG. **8** is a top plan view of the stent exterior surface polishing fixture with interior details thereof shown with broken lines to show locations of voids within the fixture.

FIG. **9** is a perspective exploded parts view of that which is shown in FIGS. **7** and **8** revealing how the stent is oriented within the stent exterior surface polishing fixture for polishing of exterior surfaces forming the outer diameter of the stent.

FIG. **10** is a perspective view of a portion of an alternative stent before any polishing of surfaces of the stent has occurred.

FIG. **11** is a perspective view of that which is shown in FIG. **10** after polishing of surfaces of the stent has been completed according to this invention.

FIG. **12** is a perspective view of a portion of that which is shown in either the stent of FIG. **11** or the stent of FIGS. **1** and **2** revealing in greater detail the exact streamlined contour of the segments of the stent after the polishing method of this invention has been completed.

FIG. **13** is a perspective view of a segment of a stent when only the portions of the stent forming the inner diameter of the stent have been polished and with surfaces forming the outer diameter of the stent left unpolished.

FIG. **14** is a perspective view of a portion of that which is shown in FIG. **10** revealing how the surfaces of the stent exhibit roughness before the polishing method of this invention is performed.

FIG. **15** is a full sectional view of that which is shown in FIG. **12** revealing further details of the streamlined contour of segments of the stent after completion of the polishing method according to this invention.

FIG. **16** is a full sectional view taken along lines **16**—**16** of FIG. **18** and showing a body lumen with a stent, polished according to this invention, located within the body lumen and radially expanded within the body lumen to support walls of the lumen.

FIG. **17** is a full sectional view of a body lumen with a non-polished or minimally polished radially expandable surgical stent located therein and revealing turbulent blood flow, restenosis and thrombus within the body lumen.

FIG. **18** is a full sectional perspective end view of the polished radially expandable surgical stent in position within a body lumen and radially expanded therein.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings, wherein like reference numerals represent like parts throughout the various different drawing figures, reference numeral **10** is directed to a radially expandable surgical stent (FIG. **1**) which has been fitted with non-radially expandable cylindrical support ends **20** at each end of the stent **10**. Surfaces of the stent **10** forming an inner diameter of the stent **10** are polished by placing the stent **10** within a stent interior polishing fixture **100** (FIGS. **3**–**6**) and flowing fluid abrasive media M through the fixture **100** with the stents **10** therein. A stent exterior polishing fixture **200** (FIGS. **7**–**9**) is also provided which is configured to polish surfaces of the stent **10** forming an outer diameter of the stent **10** by flowing the abrasive media M adjacent the exterior surfaces of the stent **10**. The abrasive media M not only polishes surfaces of the stent **10** but also alters a cross-sectional contour of stent segments **40** (FIGS. **10**–**15**) such that an inner surface **44** is streamlined to minimize disruption of bodily fluid flow passing over the inner surface **44** when the stent **10** is implanted within a body lumen L (FIGS. **16** and **18**) after removal of the cylindrical support ends **20**. The fixtures **100**, **200** and other details of the polishing method of this invention can be altered to polish surfaces of the stent **10** in various different manners and also to alter a contour of surfaces of the stent

10, such as to streamline surfaces of the stent 10, to cause surface details of the stent 10 to match any of a variety of different desired contours and with a variety of different finish smoothness. However, a preferred contour for the stent 10 and stent segments 40 (FIG. 11) of an alternative stent 30, having slightly differently configured stent segments 40 than the circumferential elements 12 and axial elements 14 of the stent 10 (FIGS. 1 and 2), is described in detail. By altering the polishing methods discussed below, stents having different contour characteristics could similarly be generated.

In essence, and with particular reference to FIGS. 11 and 12, the cross-sectional contour of each stent segment 40 is described, whether the stent segment 40 is taken from the stent 10 or from the alternative stent 30. Each stent segment 40 is an elongate construct of substantially constant cross-sectional generally rectangular form, having an outer surface 42 opposite an inner surface 44. Two lateral side surfaces including a leading surface 46 and a trailing surface 48 extend between the inner surface 44 and the outer surface 42. The inner surface 44 is provided with an inner leading edge 54 and an inner trailing edge 56 which are defined by an inner leading curve 60 and an inner trailing curve 62, respectively, with sufficiently high radii of curvature 70, 72 (FIG. 15) that the inner surface 44 is highly streamlined between the inner leading edge 54 and the inner trailing edge 56.

The outer surface 42 extends between two side edges including an outer leading edge 50 and an outer trailing edge 52. The outer leading edge 50 is defined by an outer leading curve 64 and the outer trailing edge 52 is defined by an outer trailing curve 66. The outer leading curve 64 and outer trailing curve 66 have radii of curvature 74, 76 (FIG. 15) which are less than the radii of curvature 70, 72 of the inner leading curve 60 and the inner trailing curve 62 (FIG. 12). The stent segment 40 thus has a contour which presents a highly streamlined gradually curving surface for passage of bodily fluid B (FIG. 16) there over and the outer surface 42 presents a more abrupt contour for secure positioning adjacent an inner surface S of the body lumen L (FIGS. 16 and 18).

Before polishing, the stent segments 40' (FIG. 14) of the unpolished stent 10 or alternative stent 30' have planar parallel inner and outer surfaces 44', 42' and planar parallel leading and trailing surfaces 46', 48' perpendicular to the surfaces 44', 42'. The stent segments exhibit abrupt edges 50', 52', 54', 56' between adjacent surfaces 42', 44', 46', 48'. Roughness areas R are located on the surfaces 42', 44', 46', 48'. After polishing, the stent segments 40 (FIG. 12) have greater surface smoothness and a cross-sectional contour which is more streamlined than the stent segment 40'. Specific details of the geometry and other features of the polished and streamlined stent 10 and its alternatives are incorporated by reference from U.S. patent application Ser. No. 08/839,434, filed on Apr. 10, 1997, entitled "SURGICAL STENT HAVING A STREAMLINED CONTOUR," now U.S. Pat. No. 5,718,713.

In use and operation, when a stent 10 featuring stent segments 40 of this invention is implanted into a lumen L (FIGS. 16 and 18) with the stent segments 40 embedding slightly into the inner surface S of the lumen L and supporting the lumen L, blood/fluid flow B is only slightly disrupted and restenosis and plaque buildup is minimized. When prior art stents are implanted (FIG. 17) stent segments 40 having more abrupt contours cause disruption in the blood/fluid flow B producing eddies E which further disrupt blood/fluid flow B and encourage the formation of plaque P, leading to restenosis, along the inner surface S at various locations along the inner surface S. Thrombus H is also stimulated by irregularities in surface finish exhibited by stent segments 40' of prior art stents.

With reference particularly to FIGS. 12 and 16, because the leading curves 60, 64 generally match the contour of the trailing curves 62, 66 of each stent segment 40, the stent 10 featuring the stent segment 40 can be reversed 180° with similar function in either orientation. Alternatively, should maximum streamlining of the stent segment 40 be desired, the inner surface 44 can be provided with a more airfoil-like asymmetrical contour which does not provide the leading surface 46 and trailing surface 48 as mirror images of each other, but rather provides the leading surface 46 with a smaller radius of curvature and the trailing surface 48 with a larger radius of curvature or a tapering gradual slope, somewhat analogous to that of a tear drop in cross-section. Such an asymmetrical surgical stent would necessarily only benefit from its form when implanted in a particular direction with regard to blood/fluid flow B through the lumen L.

Having thus described in detail the preferred contour and finished smoothness for the stent 10, it should be apparent that should different finished smoothness be desired, for various different purposes, various different curvatures and measurements of the contour of the stent 10 could be similarly provided. This is particularly true when utilizing the polishing method disclosed below. To accomplish polishing and streamlining of the stent 10 to exhibit the contour discussed above, or any other desired contour, the following method is utilized with the apparatus discussed in detail below.

Before polishing the stent 10 according to the method of this invention, the stent 10 is preferably slightly modified to provide additional support to the stent 10 during the polishing process. Specifically, cylindrical support ends 20 are attached to each end of the stent 10. Each cylindrical support end 20 is a cylindrical hollow substantially rigid construct preferably formed from the same material with which the circumferential elements 12 and axial elements 14 of the stent 10 are formed. Each cylindrical support end 20 includes an outer edge 22 on an end of the cylindrical support end 20 most distant from the stent 10 and an inner edge 24 opposite the outer edge 22 and adjacent the stent 10.

A plurality of ties 25 extend from the inner edge 24 to the portions of the stent 10 adjacent to each cylindrical support end 20. The ties 25 are preferably linear elongate segments of the stent 10 which are oriented in an axial direction (along arrow A of FIGS. 1 and 2) and are colinear with axial elements 14 adjacent to the cylindrical support ends 20. Preferably six ties 25 extend between the inner edge 24 and the portions of the stent 10 adjacent the cylindrical support ends 20. Each tie 25 includes an outer end 26 adjacent the inner edge 24 and an inner end 28 opposite the outer end 26 and attached to the end of the stent 10 adjacent the cylindrical support end 20.

The cylindrical support ends 20 can either be attached to the ends of the stent 10 before the polishing process or the cylindrical support ends 20 can be formed along with other portions of the stent 10 originally so that the cylindrical support ends 20 are attached to the stent 10 at all times up until the polishing process is completed. After the polishing process is completed, the cylindrical support ends 20 are removed from ends of the stent 10 along with the ties 25, providing the stent 10' (FIG. 18) in the desired configuration for implantation within a body lumen L.

The cylindrical support ends 20 are not radially expandable. Thus, the cylindrical support ends 20 help support the

stent **10** during the polishing process and prevent the stent **10** from being prematurely radially expanded. Additionally, the cylindrical support ends **20** provide a leading edge for the stent **10** during the polishing process and reduce a risk that abrasive media M flowing along surfaces of the stent **10** will cause circumferential elements **12** at ends of the stent **10** to be collapsed or to otherwise collapse the stent **10** axially (along arrow A of FIGS. **1** and **2**) due to the added rigidity of the stent **10** when the cylindrical support ends **20** are attached thereto. Preferably, inner and outer diameters of the cylindrical support ends **20** match inner and outer diameters of the stent **10**.

With reference to FIG. **2**, further details of the stent **10** with the cylindrical support ends **20** attached thereto are provided. Reference arrow C indicates a circumferential direction and reference arrows R represent the radially direction in which the stent **10** is radially expanded after removal of the cylindrical support ends **20** from the stent **10**. FIG. **2** shows the circumferential elements **12** in an undulating fashion having not yet been radially expanded, as is the case while the cylindrical support ends **20** are attached thereto. In contrast, FIG. **1** shows the circumferential elements **12** radially expanded to illustrate the difference in the configuration of the stent **10** after radial expansion. The cylindrical support ends **20** would not be attached to other portions of the stent **10** when the stent **10** has been radially expanded, along arrow R. Hence, FIG. **1** is a composite view which would not actually exist, but depicts the configuration of the cylindrical support ends **20** in perspective and a perspective view of the radially expandable surgical stent **10** after it has been radially expanded.

While various different systems could be utilized to effectively flow abrasive media past surfaces of the stent **10** for polishing, a preferred system for effectively flowing the fluid abrasive media M past surfaces of the stent **10**, and particularly for polishing surfaces of the stent **10** forming an inner diameter of the stent **10**, are provided by the stent interior polishing fixture **100** (FIGS. **3–6**). The stent interior polishing fixture **100** is a rigid construct configured to provide a means to hold a series of stents **10** motionless and provide conduits for fluid abrasive media M to flow adjacent surfaces of the stent **10** forming an inner diameter of the stent **10**. The interior polishing fixture **100** includes a top **102** parallel to and spaced from a bottom **104**. Four parallel sides **106** are oriented perpendicular to the top **102** and bottom **104**. Hence, the top **102**, bottom **104** and sides **106** form an orthorhombic rigid mass of solid material.

A series of bores **108** pass from the top **102** through to the bottom **104** of the fixture **100**. Preferably, each bore **108** is cylindrical in form and passes along a line perpendicular to the top **102** and the bottom **104**. Preferably, the bores **108** have a diameter which is similar to the inner diameter of the stent **10**. The fixture **100** is preferably not formed from a single unitary mass of material but rather from a series of rigid plates including two end plates **120** and a plurality of mid-plates **140** sandwiched between the two end plates **120**.

Each of the plates **120**, **140** is securely held together with closure bolts **112** passing through the interior polishing fixture **100** in an orientation parallel to the top **102** and bottom **104** of the fixture **100** and perpendicular to adjacent surfaces of the end plates **120**. Preferably, two closure bolts **112** are provided passing through the fixture **100** at locations which prevent the closure bolts **112** from intersecting with the bores **108**. Each closure bolt **112** includes a head **114** on an end of each bolt **112** opposite a threaded tip **116**. Wing nuts **118** are provided which thread onto the threaded tip **116**. The closure bolts **112** can pass through the plates **120**, **140** forming the fixture **100** with the head **114** of each closure bolt **112** adjacent one of the end plates **120** and the wing nuts **118** threaded onto the closure bolts **112** adjacent the opposite end plate **120**. By tightening the wing nuts **118** against the end plate **120**, the plates **120**, **140** are securely sandwiched together without motion.

The bores **108** are aligned to pass between an end plate **120** and a mid-plate **140** or between two adjacent mid-plates **140**. In this way, access is provided to a cylindrical chamber **135** within the bore **108** when the plates **120**, **140** of the interior polishing fixture **100** are separated away from each other. Preferably, three mid-plates **140** are provided between the two end plates **120** and five bores **108** are provided at each transition between an end plate **120** and an adjacent mid-plate **140** and between adjacent mid-plates **140**, such that a total of twenty bores **108** are provided passing from the top **102** to the bottom **104** of the interior polishing fixture **100**.

With particular reference to FIG. **5**, specific details of each end plate **120** are provided. Each end plate **120** is a unitary rigid mass of material which forms a portion of the interior polishing fixture **100**. Each end plate **120** includes an outer surface **122** which does not include any portion of a bore **108** thereon. Each end plate **120** includes a bottom **124** parallel to and spaced from a top **128** which form portions of the top **102** and bottom **104** of the interior polishing fixture **100**. Each end plate **120** also includes lateral sides **126** parallel to each other and oriented perpendicular to the bottom **124** and top **128**.

An inner surface **130** is provided on the side of the end plate **120** opposite the outer surface **122**. This inner surface **130** is similarly formed on each of the two end plates **120**. The inner surface **130** is contoured to include portions of the bores **108** therein. Each inner surface **130** includes a flat plane **132** defining portions of the inner surface **130** which do not include portions of the bores **108** therein. Two bolt holes **133** pass through the inner surface **130** and entirely through to the outer surface **122** of each end plate **120**. The bolt holes **133** have a diameter which accommodates passage of the closure bolts **112** there through. The bolt holes **133** are preferably located at a position intermediate between the bottom **124** and top **128** of the end plate **120** and between a lateral side **126** of the end plate **120** and a closest bore **108**. Alternatively, the bolt holes **133** can be located at any location on the inner surface **130** where the flat plane **132** is provided, rather than a portion of a bore **108**.

Each bore **108** includes a void defined by a cylindrical chamber **135** therein. The cylindrical chamber **135** is formed by having a cylindrical chamber wall **134** contoured into the inner surface **130** of each end plate **120**. Preferably, with five bores **108** passing between each end plate **120** and an adjacent mid-plate **140**, five cylindrical chamber walls **134** are formed in the inner surface **130**. The cylindrical chamber wall **134** is semicylindrical in form providing exactly one-half of the cylindrical chamber **135**. The cylindrical chamber wall **134** does not extend all the way up to the top **128** or to the bottom **124** of the end plate **120**. Rather, the cylindrical chamber wall **134** forms an interior detail of one of the bores **108** which does not extend to the top **102** and bottom **104** of the interior polishing fixture **100**.

The cylindrical chamber wall **134** preferably has a diameter similar to an outer diameter of the stent **10**. The cylindrical chamber wall **134** extends from a top chamber end **136** to a bottom chamber end **137** (FIG. **4**). Above the top chamber end **136** a top cylindrical bore wall **138** (FIG. **5**) is provided forming a portion of the bore **108** extending

from the cylindrical chamber **135** up to the top **102** of the fixture **100**. A bottom cylindrical bore wall **139** (FIG. **5**) similarly extends from the bottom chamber end **137** to the bottom **104** of the interior polishing fixture **100**.

The top cylindrical bore wall **138** and bottom cylindrical bore wall **139** form exactly half of the cylindrical bore **108** leading into and out of the cylindrical chamber **135**. The top chamber end **136** and bottom chamber end **137** provide a transition between the larger diameter of the cylindrical chamber **135** and the smaller diameter of the bores **108**. With the top chamber end **136** and bottom chamber end **137** spaced apart similar to an axial length of the stent **10**, a stent **10** can be located within the cylindrical chamber **135** with the outer diameter of the stent **10** adjacent the cylindrical chamber wall **134** and with the cylindrical support ends **20** of the stent **10** adjacent the top chamber end **136** and bottom chamber end **137**. In this position, the inner diameter of the stent **10** is aligned with the bore walls **138, 139** forming the bores **108**.

The mid-plates **140** are similar to the end plates **120** except that each mid-plate **140** includes two contoured surfaces **142** each similar in contour to the contour provided by the inner surface **130** of each end plate **120**. The mid-plates **140** include a bottom **144** parallel to and spaced from a top **148** with two parallel lateral sides **146** oriented perpendicular to the bottom **144** and top **148**.

With particular reference to FIG. **6**, other portions of the stent polishing apparatus which attach to the interior polishing fixture **100** are described in detail. A hose **150** is located adjacent the top **102** of the interior polishing fixture **100**. The hose **150** provides a source for fluid abrasive media M which can lead from a reservoir up to the top **102** of the fixture **100**. A lower end **151** of the hose **150** is located adjacent a manifold plate **152**. The manifold plate **152** is a rigid construct which is configured to seal against the top **102** of the fixture **100** with a manifold chamber **153** therein provided in fluid communication with each of the bores **108** in the interior polishing fixture **100**. The. manifold chamber **153** is also open to the interior of the hose **150** so that fluid abrasive media M can flow through the hose **150**, out of the lower end **151** of the hose **150** and into the manifold chamber **153**; where it can then flow into each of the bores **108** in the interior polishing fixture **100**.

A top clamp plate **154** is located over the manifold plate **152** and secures the manifold plate **152** to the top **102** of the fixture **100**. A hose opening **155** is located in the top clamp plate **154** so that the hose **150** can still access the manifold chamber **153**. A bottom clamp plate **156** is located adjacent the bottom **104** of the fixture **100**. The bottom clamp plate **156** includes a central opening **157** which leaves the bores **108** in the bottom **104** unblocked. A series of clamp bolts **158** with wing nuts **159** pass through the top clamp plate **154** and bottom clamp plate **156** and can be threaded together, drawing the bottom clamp plate **156** and top clamp plate **154** toward each other and securing the manifold plate **152** and hose **150** adjacent the top **102** of the interior polishing fixture **100**.

In use and operation, the interior polishing fixture **100** is utilized to polish surfaces forming an inner diameter of the stent **10** in the following manner. Initially, the closure bolts **112** are removed from the fixture **100** and the end plates **120** and mid-plates **140** are each separated from each other. Each cylindrical chamber **135** is then preferably provided with a separate stent **10** and the end plates **120** and mid-plates **140** are placed adjacent each other with the closure bolts **112** in place securing the plates **120, 140** together. The manifold plate **152** is then placed over the top **102** of the fixture **100** with the hose **150** interfacing with the manifold plate **152**. The top clamp plate **154** and bottom clamp plate **156** are then oriented over the top **102** and bottom **104**, respectively, of the fixture **100** and the wing nuts **159** are tightened to secure the manifold plate **152** and hose **150** in position adjacent the top **102** of the fixture **100**.

Fluid abrasive media M is then passed (along arrow F) through the hose **150** into the manifold chamber **153**, through the bores **108** and into the cylindrical chamber **135** where the fluid abrasive media M flows adjacent surfaces forming the inner diameter of the stent **10**. The media M then flows out of the bores **108** and through the central outflow opening **157** in the bottom clamp plate **156** (along arrow D).

Preferably, the fluid abrasive media M flows through the fixture **100** and past the inner diameter of the stent **10** for a desired amount of time and then the fluid abrasive media M is caused to flow in a reverse direction against the inner diameter of the stent **10**. Reversal of flow of the abrasive media M can be accomplished by removing the fixture **100** from the clamp plates **154, 156**, reversing the fixture **100** and replacing the fixture **100** within the clamp plates **154, 156** with the top clamp plate **154** and manifold plate **152** adjacent the bottom **104** of the fixture **100**. Alternatively, the hose **150** and a source of fluid abrasive media M can be configured to allow flow in both directions through the bores **108** of the fixture **100**.

If a streamlined contour is desired for surfaces forming the inner diameter of segments **40** (FIG. **12**) forming the stent **10**, rather than mere polishing of surfaces of the stent **10**, the fluid abrasive media M would be allowed to flow through the fixture **100** for a greater amount of time or the fluid abrasive media M could be provided with particles having a greater amount of abrasiveness. If a streamlined contour of symmetrical form is desired, the amount of time with which the media M flows in a first direction should approximate the amount that it flows in a reverse direction.

Polishing of surfaces of the stent **10** can be further enhanced by ultrasonically vibrating the abrasive media M as the abrasive media M flows through the fixture **100** and adjacent surfaces of the stent **10**. Specifically, the hose **150** and a source of fluid abrasive media M on an end of the hose **150** opposite the lower end **151** can be fitted with an ultrasonic vibration generation device which causes high frequency agitation of the fluid abrasive media M as it flows through the fixture **100**. Another parameter which can be utilized to enhance the effectiveness of the fluid abrasive media M is to supply the fluid abrasive media M at a pressure greater than atmospheric pressure as the fluid abrasive media M passes through the fixture **100**. Such enhanced pressure can be provided with pistons in communication with the fluid abrasive media M or other pumps or other pressure generation means acting on the fluid abrasive media M before or during fluid abrasive media M flow through the hose **150** and into the fixture **100**.

The fluid abrasive media M can either exit the bores **108** of the fixture **100** into an atmospheric pressure region without any specific enclosures or it can be fitted with an outlet hose similar to the hose **150** for collection of the fluid abrasive media M. If desired, the fluid abrasive media can oscillate back and forth through the bores **108** rather than flowing continuously in a first direction through the bores **108** and then being reversed in direction to flow in an opposite direction through the bores **108**.

The sizing of the bores **108** to have a similar diameter to the inner diameter of the stent **10** and the chamber **135** to

have a similar diameter to the outer diameter of the stent **10** prevents the fluid abrasive media M from flowing past surfaces forming the outer diameter of the stent **10** and maintains surfaces of the stent **10** forming the outer diameter in a substantially unpolished and unstreamlined form. It has been found to be particularly advantageous that the inner diameter of the stent **10** be polished and streamlined such that blood B or body fluids can pass through a lumen L where the stent **10** is located and radially expanded in a manner which decreases turbulence of blood B flowing through the lumen L (FIGS. **16** and **17**).

An alternative stent segment **90** is shown in FIG. **13** where only the inner diameter of the stent segment **90** has been polished and streamlined. An outer surface **92** remains substantially planar with outer edges **96** abruptly transitioning to the inner edges **98** leading to the inner surface **94** which has been streamlined. Areas of roughness R can either remain on the outer surface **92** where the stent segment **90** is located adjacent an inner surface S of the lumen L (FIGS. **16** and **17**) or be polished merely to remove roughness R but not to streamline or round off edges of the stent segment **90**. Such an alternative stent segment **90** would typically result in utilization of the stent interior polishing fixture **100** alone, with little or no utilization of the stent exterior polishing fixture **200** described below.

While various different parameters can be selected in performing the polishing process disclosed herein, it has been found effective and preferable to have abrasive media particle sizes between 0.008 and 0.0003 inches. It has been found preferable to maintain an elevated pressure between 300 and 800 pounds per square inch. An abrasive media M which has been found to be effective is aluminum oxide or silicon carbide. Alternatively, diamond particles could be utilized.

More specifically, successful tests were run of a fixture **100** similar to that disclosed herein utilizing aluminum oxide with a particle size of 0.0007 inches at a pressure of 500 pounds per square inch with a total process time of thirteen minutes (7.5 minutes each direction) and a desirable surface finish with streamlining of stainless steel stent segments **40** similar to that shown in FIGS. **12** and **15** resulted. In another test, silicon carbide was utilized with a particle size of 0.006 inches at 500 pounds per square inch with a total process time of thirteen minutes and similar contours to those shown in FIGS. **12** and **15** resulted. Specifically, surface roughness R was reduced to elimination of any prominences greater than 5 micro inches above adjacent portions of the surfaces.

Once the stents **10** have been polished by flow of the fluid abrasive media M through the fixture **100**, the hose **150** and other apparatus adjacent the fixture **100** are removed and the individual plates **120, 140** are separated from each other for removal of the stents **10** therefrom. The cylindrical end supports **20** are then removed from the stents **10**, providing a polished stent **10'** (FIG. **18**) which is now ready for implantation and radial expansion within a body lumen L as is known in the art.

With particular reference to FIGS. **7–9**, details of the stent exterior polishing fixture **200**, which is configured to particularly provide polishing for surfaces forming an outer diameter of the stent **10**, are described in detail. The stent exterior polishing fixture **200** is shown in FIGS. **7–9** as having a void therein for supporting only a single stent **10** for polishing therein. However, the exterior polishing fixture **200** could be modified to include multiple separate voids and multiple separate plates as in the case of the interior polishing fixture **100** such that multiple stents **10** can be polished simultaneously within the stent exterior polishing fixture **200**. For convenience, the details of the stent exterior polishing fixture **200** will be described for an embodiment where only a single void for a single stent **10** is provided within the stent exterior polishing fixture **200**.

The exterior polishing fixture **200** is a solid rigid mass of material having a top **202** parallel to and spaced from a bottom **204** with sides **206** extending perpendicularly between the top **202** and the bottom **204**. Multiple slanted bores **208** pass through the top **202** and bottom **204** and communicate together such that fluid abrasive media M can flow entirely through the fixture **200** from the top **202** to the bottom **204**, in a manner similar to that described above with respect to the interior polishing fixture **100**.

The exterior polishing fixture **200** is formed from two identical end plates **210** having an outer surface **212** extending perpendicularly between a bottom **214** and a top **218** which form portions of the bottom **204** and top **202**, respectively, of the exterior polishing fixture **200**. A lateral surface **216** defines surfaces of the end plate **210** perpendicular to the bottom **214** and top **218** and also perpendicular to the outer surface **212**.

A cylindrical recess **220** somewhat analogous to the cylindrical chamber **135** in the interior polishing fixture **100** is located within the exterior polishing fixture **200** in fluid communication with the slanted bores **208**. The cylindrical recess **220** is formed between the two end plates **210** such that the cylindrical recess **220** is in fact formed in an inner surface **230** parallel to and spaced from the outer surfaces **212** of the two end plates **210**. Each inner surface **230** includes a flat plane **232** defining portions of the inner surface **230** where the cylindrical recess **220** is not located and a cylindrical recess wall **234** defining exactly one-half of the cylindrical recess **220**. The cylindrical recess wall **234** is preferably semi-cylindrical in form and has a diameter greater than an outer diameter of the stent **10**.

A top blind bore **240** extends up from the cylindrical recess **220** between the multiple slanted bores **208**. The top blind bore **240** extends up to a top bore wall **242** perpendicular to the cylindrical recess wall **234** of the cylindrical recess **220**. A bottom blind bore **250** similar to the top blind bore **240** but below the bottom of the cylindrical recess **220** is also located within the exterior polishing fixture **200**. The bottom blind bore **250** includes a bottom bore wall **252** parallel to the top bore wall **242**.

Between the top bore wall **242** and bottom bore wall **252** and the cylindrical recess wall **234** two similar collar support regions **260** are located. The top blind bore **240**, bottom blind bore **250** and two collar support regions **260** are each cylindrical in form but exhibit different diameters extending away from a central axis common with the cylindrical recess **220**. A recess edge **262** defines a diameter transition between the cylindrical recess wall **234** and the two collar support regions **260**. A bore edge **264** is located at a transition between the collar support regions **260** and the two blind bores **240, 250**.

Preferably, the slanted bores **208** extend from the top **202** and the bottom **204** up into the collar support regions **260**. Preferably, two slanted bores **208** are located within each end plate **210** such that a total of four slanted bores **208** pass from the top **202** into the cylindrical recess **220** and four slanted bores **208** pass from the bottom **204** into the cylindrical recess **220**.

The cylindrical recess wall **234** has a diameter greater than an outer diameter of the stent **10**. The collar support regions **260** have a diameter similar to an outer diameter of

the stent **10**. The blind bores **240**, **250** have a diameter similar to an inner diameter of the stent **10**.

A shaft **270** is provided having a length similar to a distance between the top bore wall **242** and the bottom bore wall **252** and having a diameter similar to a diameter of the blind bores **240**, **250** and the inner diameter of the stent **10**. Thus, the stent **10** can be placed on the shaft **270** with the inner diameter of the stent **10** adjacent the shaft **270**. The shaft **270** includes a top end **272** parallel to and spaced from a bottom end **274** with a cylindrical surface **276** sized to be located adjacent the inner diameter of the stent **10**. The shaft **270** is located within the exterior polishing fixture **200** with the top end **272** within the top blind bore **240** and the bottom end **274** within the bottom blind bore **250** when the exterior polishing fixture **200** is in use for polishing exterior surfaces of the stent **10**.

An upper collar **280** is provided having an inner surface **282** with a diameter similar to a diameter of the cylindrical surface **276** of the shaft **270**. The upper collar **280** includes an outer surface **284** with a diameter similar to a diameter of the collar support regions **260** and the outer diameter of the stent **10**. The upper collar **280** is a hollow cylindrical rigid construct extending from a circular top edge **286** to a circular bottom edge **288**. The upper collar **288** has a length between the top edge **286** and the bottom edge **288** which causes the upper collar **280** to be longer than a distance within each collar support region **260** from the recess edge **262** to the bore edge **264**. Thus, when the upper collar **280** is located on the shaft **270** within the fixture **200** the upper collar **280** extends down into the cylindrical recess **220** somewhat. A lower collar **290** is provided with a form similar to that of the upper collar **280**.

Preferably, the cylindrical recess **220** has a length between the recess edges **262** which is slightly greater than a length of the stent **10** and actually includes a length of the stent **10** and a length of portions of each collar **280**, **290** which extend from the recess edges **262** into the cylindrical recess **220**. Thus, when the shaft **270** is located within the exterior polishing fixture **200** with the top end **272** within the top blind bore **240** and the bottom end **274** within the bottom blind bore **250** and with the collars **280**, **290** located upon the shaft **270** and within the collar support regions **260** (as shown in FIG. **7**), sufficient space is provided between the upper collar **280** and the lower collar **290** for the stent **10** to be placed over the shaft **270** and between the upper collar **280** and the lower collar **290** without any axial motion of the stent **10** between the collars **280**, **290** within the exterior polishing fixture **200** allowed.

Preferably, the shaft **270**, upper collar **280** and lower collar **290** are each separate pieces so that the stent **10** can be easily placed upon the shaft **270** with the collars **280**, **290** also on the shaft **270** adjacent ends of the stent **10**. The shaft **270**, collars **280**, **290** and stent **10** can then be simultaneously placed together within the cylindrical recess **220**, top blind bore **240**, bottom blind bore **250** and collar support regions **260** as the two end plates **210** of the exterior polishing fixture **200** are closed together.

Preferably, closure bolts similar to the closure bolts **212** of the interior polishing fixture **100** are utilized to secure the end plates **210** together. Also, a clamping system, manifold plate and hose are provided in a manner similar to that discussed above with respect to the interior polishing fixture **100** to deliver fluid abrasive media M through the slanted bores **208** and into the cylindrical recess **220**.

Because the cylindrical recess **220** has a diameter greater than the outer diameter of the stent **10**, and because the shaft **270** prevents fluid abrasive media M from flowing adjacent interior surfaces of the stent **10**, the fluid abrasive media M is caused to flow exclusively over surfaces of the stent **10** forming the outer diameter of the stent **10**. As with the use of the interior polishing fixture **100** discussed above, various different fluid abrasive media M can be utilized with different pressures, durations, particle sizes, and ultrasonic vibration, as required to produce a desired finished surface for outer surfaces of the stent **10**. Preferably, the outer diameter of the stent **10** is polished to have a smooth surface but is not significantly streamlined. Rather the stent segments **40** are provided with relatively abrupt leading and trailing edges **50**, **52** (FIGS. **12** and **15**) so that the stent **10** will remain securely in place when radially expanded within a body lumen L, without sliding along the inner surface S of the body lumen L, but preferably does not have patches of roughness R (FIGS. **13** and **14**) which might cause irritation of the body lumen L and lead to thrombus, restenosis or other detrimental complications.

Preferably, the slanted bores **208** enter into the cylindrical recess **220** at a location where the upper collar **280** and lower collar **290** are provided. Thus, extreme upper portions of the cylindrical recess **220** provide a zone where the fluid abrasive media M can flow laterally between adjacent slanted bores **208** and fill the cylindrical recess **220** before the fluid abrasive media M flows down to the cylindrical recess **220** and comes into contact with surfaces of the stent **10** forming the outer diameter of the stent **10**. In this way, all locations within the cylindrical recess **220** are provided with fluid abrasive media M for polishing, without any vacant regions in the abrasive media M flow.

While the exterior polishing fixture **200** has been separately disclosed and described with respect to a preferred interior polishing fixture **100**, it is understood that a fixture could be provided which allows abrasive media M to flow simultaneously adjacent an inner diameter and an outer diameter of the stent **10** such that a single composite fixture rather than two separate fixtures would be provided. The benefits of such a composite fixture, including overall simplification of the stent polishing process would necessarily be compared with the added complexity of such a fixture and difficulties associated with securing the stent **10** in position within such a fixture and adequately supporting the stent **10** such that the stent **10** is not damaged during high pressure flow of the abrasive media M adjacent surfaces of the stent **10**.

Other further modifications to the fixtures **100**, **200** and the polishing process could also be resorted to without departing from the scope of the invention. The specific embodiments disclosed herein are provided merely by way of example and to provide a best mode and preferred embodiment for practicing this invention and should not be considered as further limiting the claims included herein below.

What is claimed is:

1. A method for polishing surfaces of a cylindrical radially expandable surgical stent including the steps of:

selecting an abrasiveness for particles within a fluid abrasive media;

providing a source of the fluid abrasive media;

orienting the radially expandable surgical stent with a central axis thereof extending in an axial direction;

subjecting the fluid abrasive media to elevated pressure substantially between 300 and 800 p.s.i.; and

flowing the abrasive media past the radially expandable surgical stent in an axial direction with the abrasive

media coming into physical contact with the surface of the radially expandable surgical stent, wherein the step of flowing includes maintaining the flowing past an inner stent surface for a length of time sufficient to abrade the edges of the inner stent surface until said edges are streamlined in shape, and maintaining the flowing past an outer stent surface for a length of time sufficient only to polish the outer stent surface.

2. A method for polishing surfaces of a cylindrical radially expandable surgical stent including the steps of:

selecting an abrasiveness for particles within a fluid abrasive media;

providing a source of the fluid abrasive media;

orienting the radially expandable surgical stent with a central axis thereof extending in an axial direction;

subjecting the fluid abrasive media to elevated pressure substantially between 300 and 800 p.s.i.; and

flowing the abrasive media past the radially expandable surgical stent in an axial direction with the abrasive media coming into physical contact with the surface of the radially expandable surgical stent, wherein the step of flowing includes maintaining the flowing for a length of time sufficient to abrade the edges of an inner stent surface until said edges have a greater radii of curvature than radii of curvature of outer edges bordering an outer surface of the stent.

3. A method for polishing surfaces of a cylindrical radially expandable surgical stent having a central axis, comprising:

providing a source of the fluid abrasive media;

flowing the abrasive media past the stent in an axial direction with the abrasive media coming into physical contact with the surfaces of the stent; and maintaining the flowing past an inner stent surface for a length of time sufficient to abrade the edges of the inner stent surface until said edges are streamlined in shape, wherein the flowing of the abrasive media past an outer stent surface is maintained for a length of time sufficient only to polish the outer stent surface.

4. A method for polishing surfaces of a cylindrical radially expandable surgical stent having a central axis, comprising:

providing a source of the fluid abrasive media;

flowing the abrasive media past the stent in an axial direction with the abrasive media coming into physical contact with the surfaces of the stent; and maintaining the flowing past an inner stent surface for a length of time sufficient to abrade the edges of the inner stent surface until said edges are streamlined in shape, wherein the step of flowing includes maintaining the flowing for a length of time sufficient to abrade the edges of an inner stent surface until said edges have a greater radii of curvature than radii of curvature of outer edges bordering an outer surface of the stent.

5. A method for polishing surfaces of a cylindrical radially expandable surgical stent having a central axis, comprising:

providing a fluid abrasive media containing particles having a size substantially between 0.0003 and 0.008 inches;

providing a source of the fluid abrasive media;

maintaining the fluid abrasive media at an elevated pressure substantially between 300 and 800 p.s.i.;

flowing the abrasive media past the stent in an axial direction with the abrasive media coming into physical contact with the surfaces of the stent;

maintaining the flowing past an inner stent surface for a length of time sufficient to abrade the edges of the inner stent surface until said edges are streamlined in shape; and

maintaining the flowing past an outer stent surface for a length of time sufficient to polish the outer stent surface.

* * * * *

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United States Patent [19]

Klein

[11] Patent Number: 5,788,558

[45] Date of Patent: Aug. 4, 1998

[54] **APPARATUS AND METHOD FOR POLISHING LUMENAL PROSTHESES**

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[73] Assignee: **Localmed, Inc.**, Palo Alto, Calif.

[21] Appl. No.: **556,341**

[22] Filed: **Nov. 13, 1995**

[51] **Int. Cl.**[6] **B24B 31/00**

[52] **U.S. Cl.** **451/36**; 451/113; 451/61

[58] **Field of Search** 451/559, 36, 37, 451/104, 113, 61

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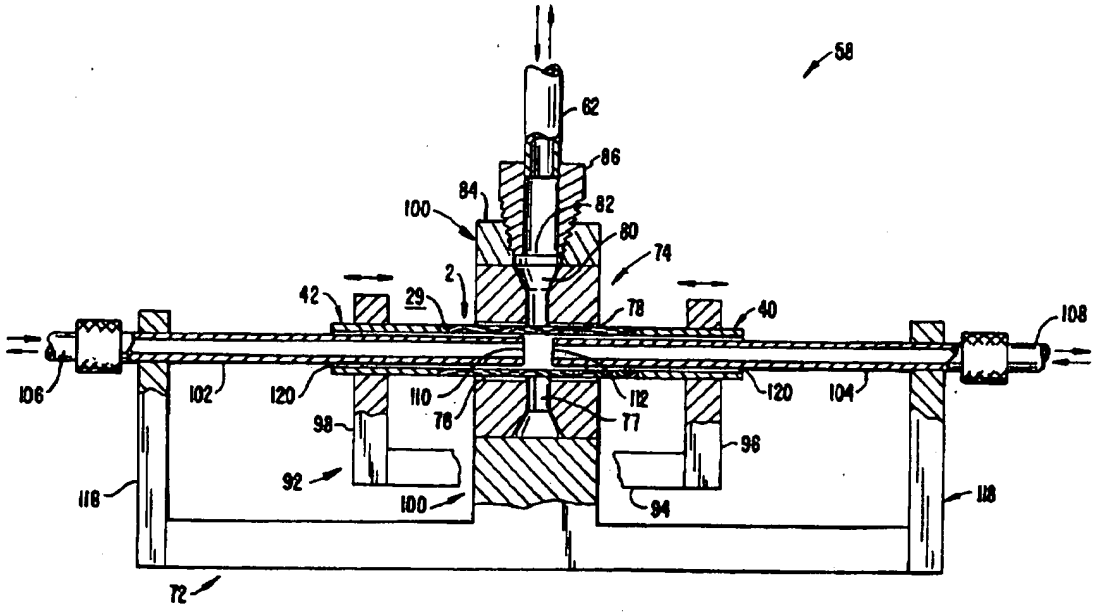
Primary Examiner—Robert A. Rose

Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP

[57] **ABSTRACT**

Methods and apparatus for deburring and rounding edges and polishing surfaces of radially expansible lumenal prostheses, such as stents and grafts, are provided. A stent (**2**) is mounted onto a polishing apparatus (**58**) and a flowable abrasive slurry is extruded through the apparatus in abrading contact with inner and outer surfaces (**28**, **29**) and circumferential openings (**30**) in the stent. To polish the cut surfaces (**32**) and edges (**34**, **36**) surrounding the openings, the abrasive slurry is introduced into an inner lumen (**26**) of the stent and extruded radially outward through the openings. The inner and outer wall surfaces **28**, **29** are preferably pre-polished prior to cutting the slot pattern (i.e., openings **30**) in the stent.

50 Claims, 7 Drawing Sheets



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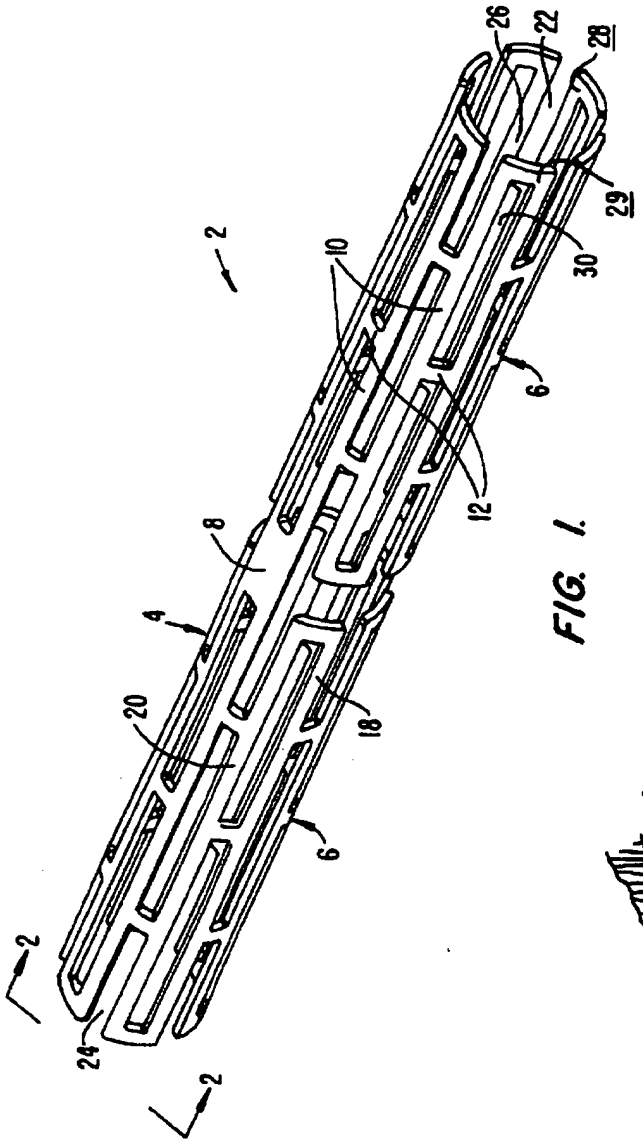


FIG. 1.

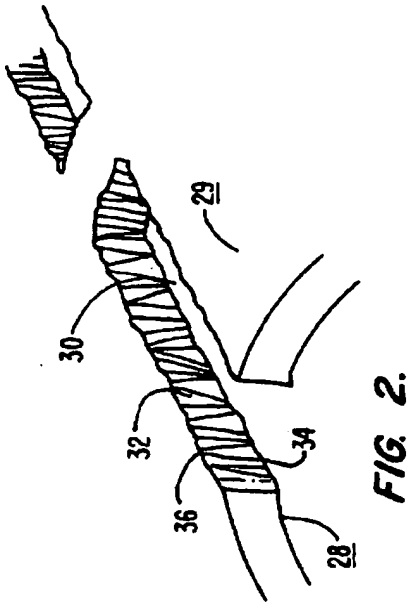


FIG. 2.

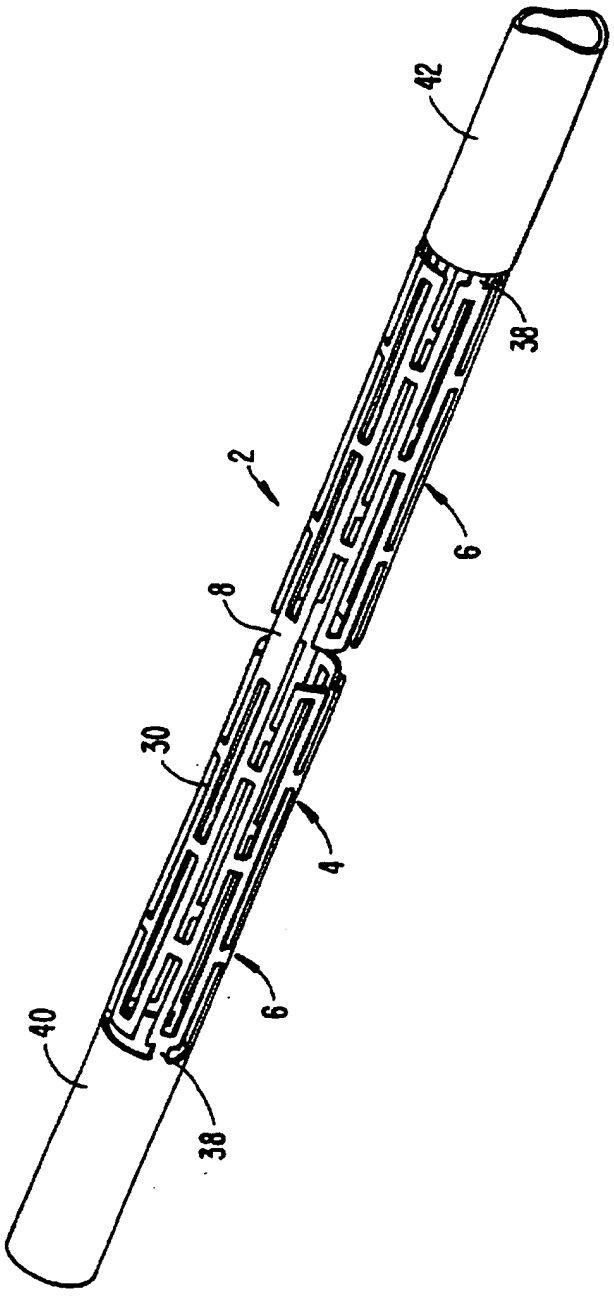
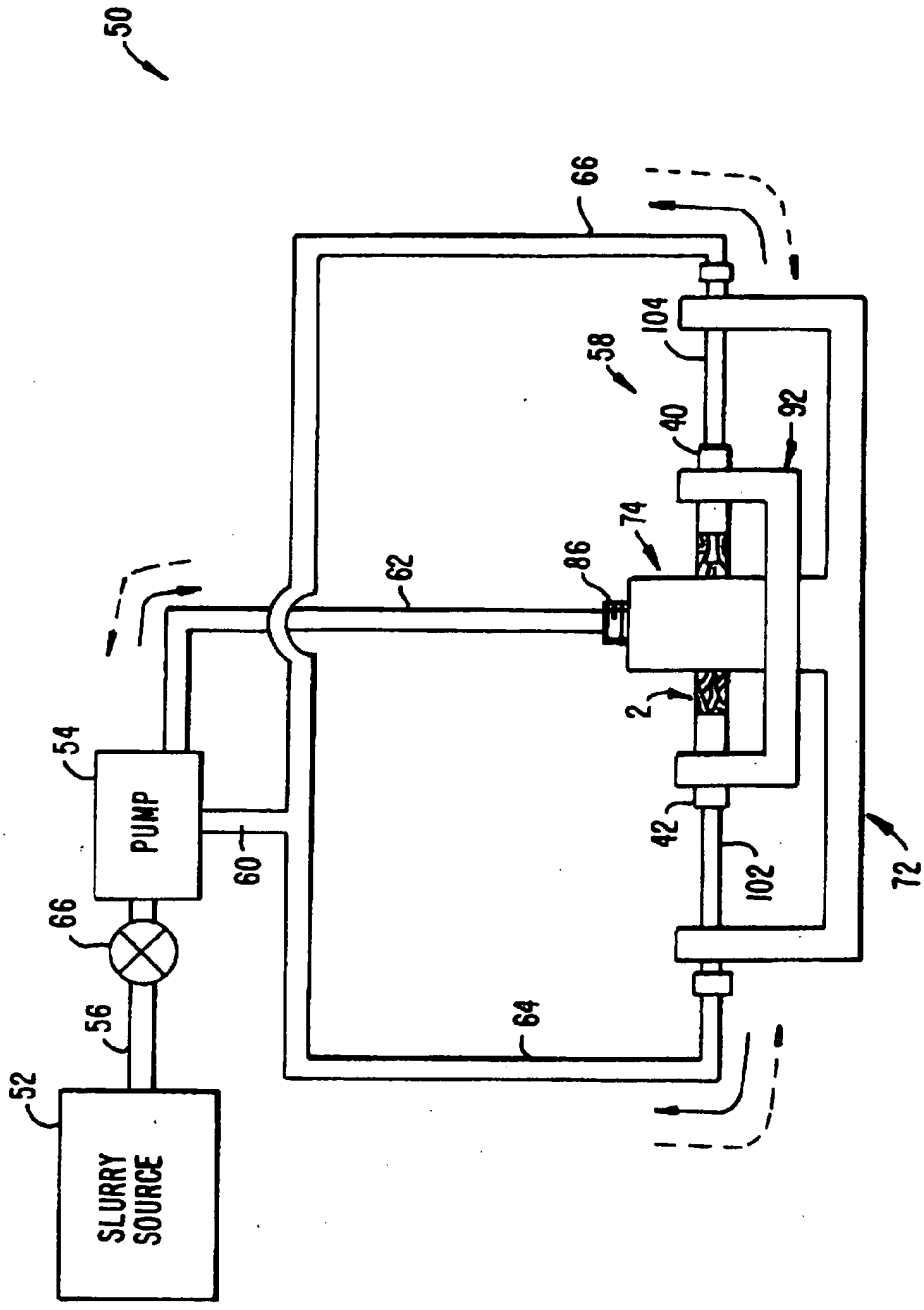


FIG. 3.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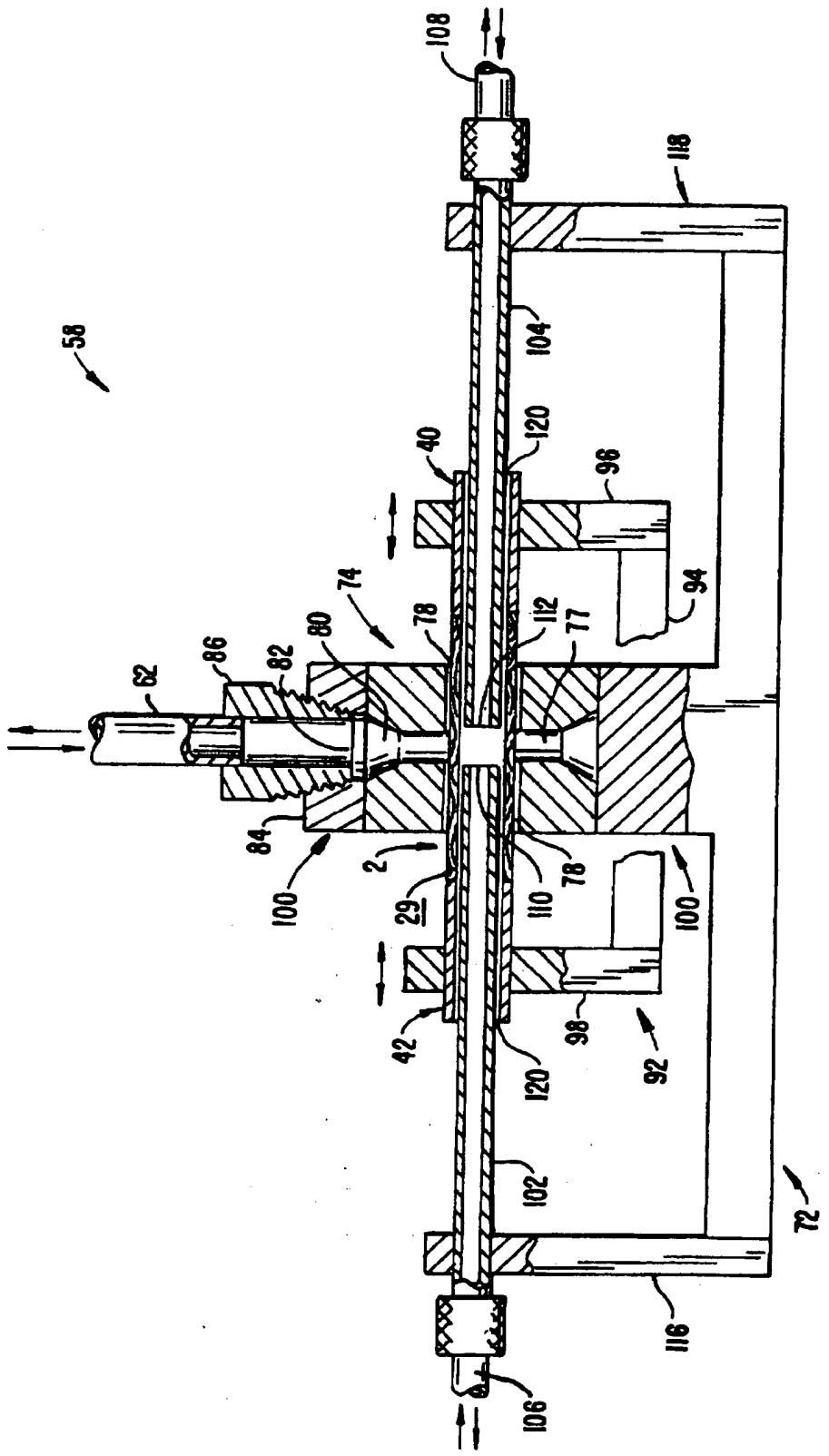
SLURRY SOURCE

FIG. 4.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112
77
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92
120
102
72
116
106

FIG. 5.

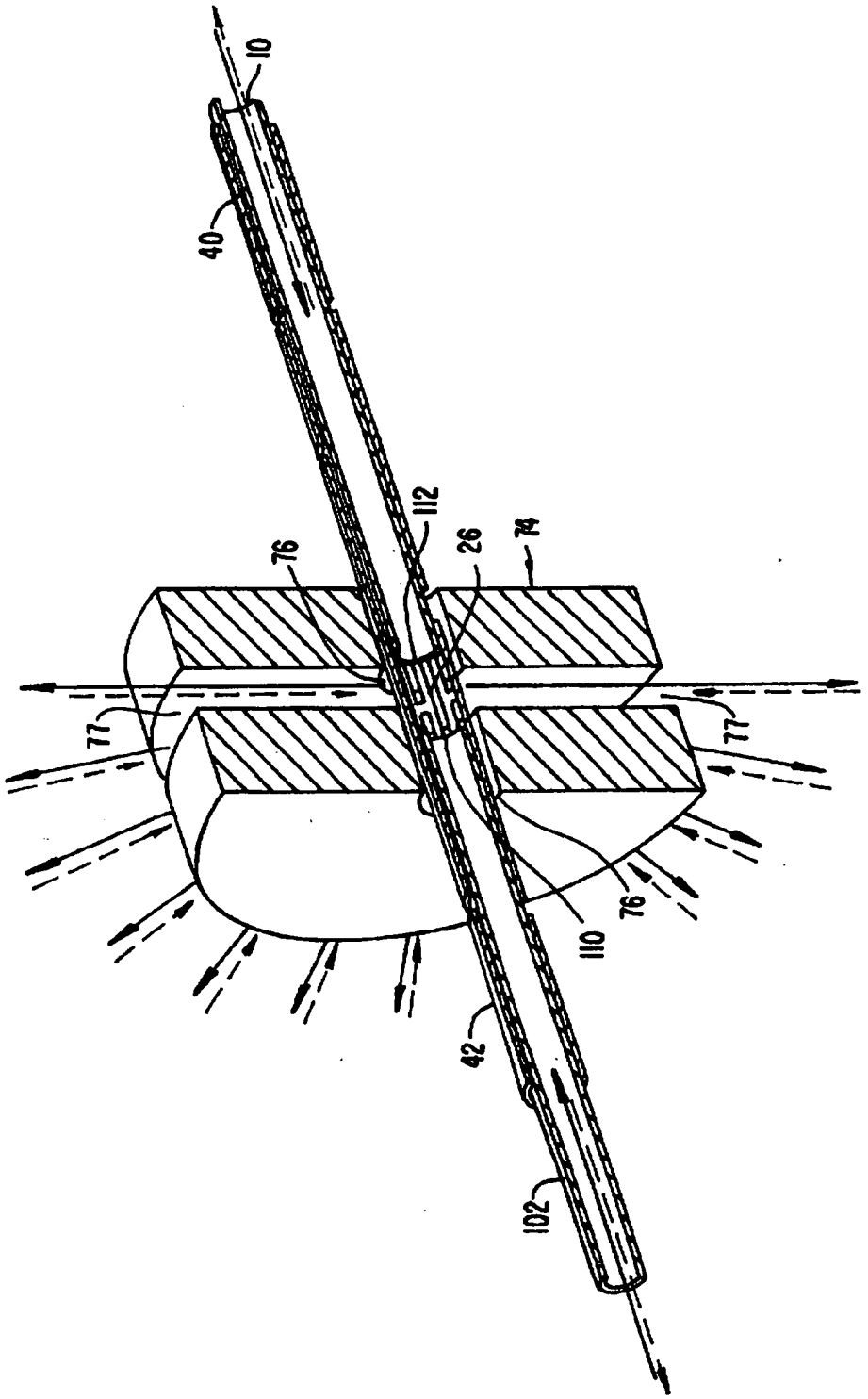

FIG. 6.

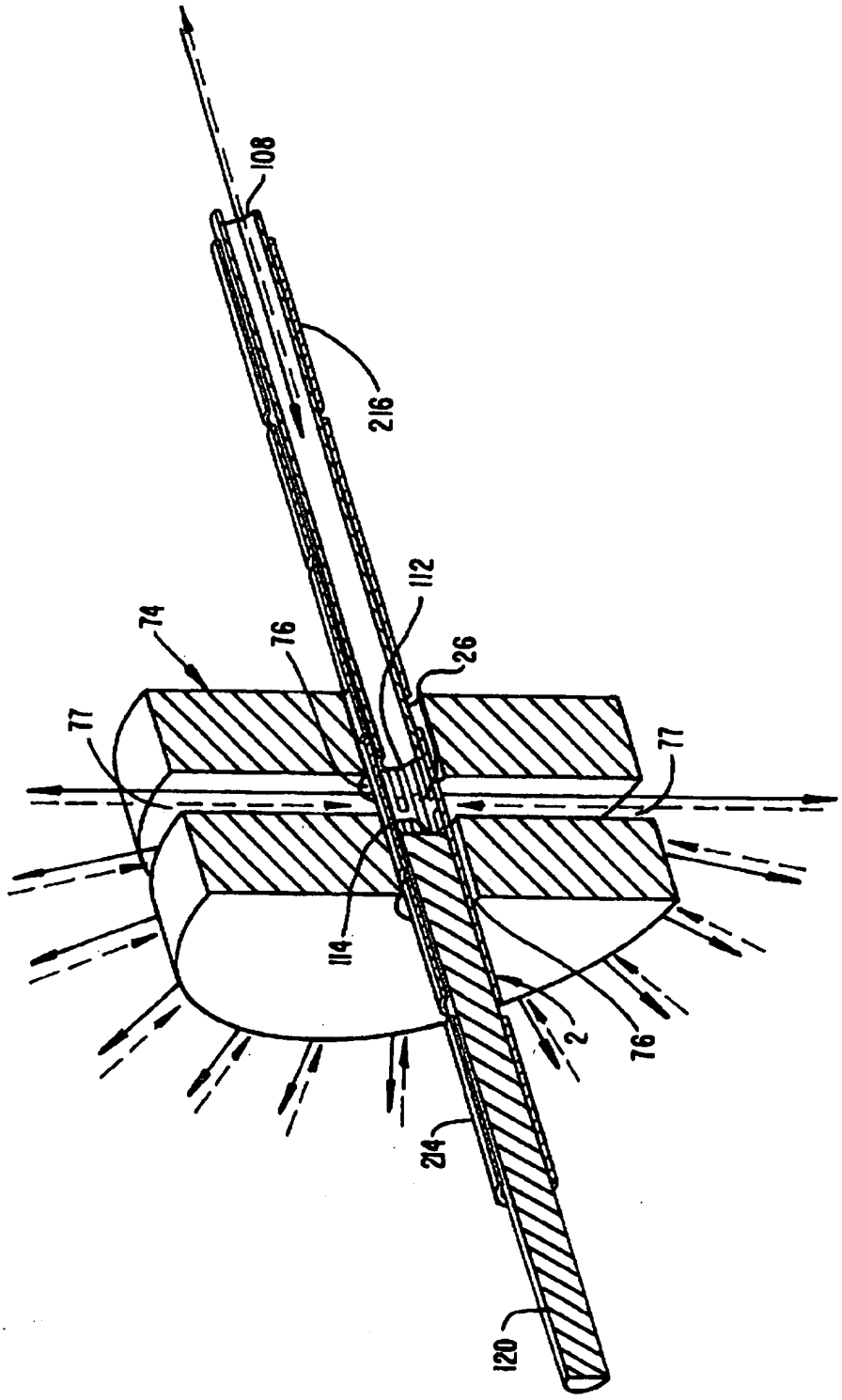

FIG. 7.

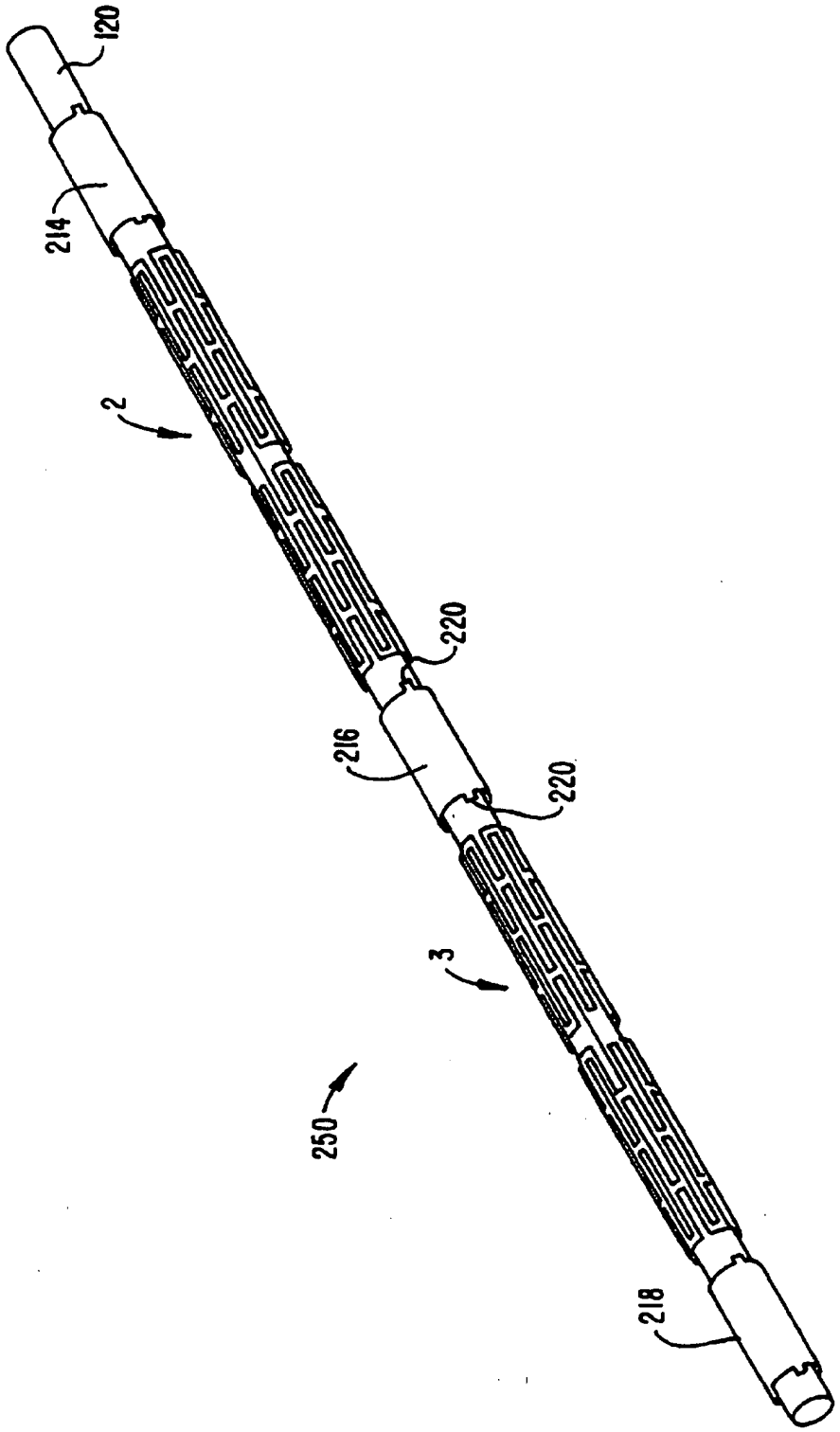

FIG. 8.

APPARATUS AND METHOD FOR POLISHING LUMENAL PROSTHESES

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to radially expansible lumenal prostheses and more particularly to an apparatus and method for polishing the cut edges and wall surfaces of lumenal prostheses.

Lumenal prostheses, commonly known as stents, are tubular shaped devices which function to hold open a segment of a blood vessel or other anatomical lumen. These stents are provided for a variety of medical purposes. For example, stents can be placed in various body lumens, such as blood vessels, and the ureter, urethra, biliary tract, and gastrointestinal tract, for maintaining patency. Stents are particularly suitable for supporting dissections in the arterial tissue that may occur during, for example, balloon angioplasty procedures. Such dissections can occlude an artery and prevent the flow of blood therethrough. In addition, stents may be used as grafts for supporting weakened bloods vessels, such as in aortic aneurysm repair procedures.

Many types of stents are typically manufactured from a tubular material, such as hypodermic tubing made of stainless steel, or a nickel titanium alloy (i.e., nitinol), that when formed into a stent can be made to expand radially. Such stents have the mechanical hoop strength to maintain lumen patency and/or mechanically augment the lumenal wall strength. Stents of this configuration typically comprise a hollow tubular body member with a plurality of struts or beam elements which deform as the stent expands radially from a small introducing diameter to a larger deployed diameter. After radial expansion, the struts or beam elements define openings therebetween having cut edges and side surfaces that come into contact with the vessel wall and the blood stream.

An important parameter in manufacturing and finishing stents is the smoothness of the inner and outer surfaces of the body member and the surfaces and edges of the openings between the beams or body elements. This is particularly important for several reasons. Foremost among these reasons is that rough, metallic surfaces may present foci for platelet aggregation, which is known to result in thrombus formation and may lead to abrupt closure of the stented vessel unless a strict anticoagulation regime is followed, which may lead to yet other complications. Also, malleable stents, such as stainless steel stents, are often deployed using standard or high pressure angioplasty balloons. Such balloons are made from very thin and strong polymeric materials which have been known to burst when expanding a malleable stent due to the sharp edges on the stent cutting into the balloon and causing it to rupture. In addition, sharp metallic edges on the stent may injure or traumatize the blood vessel walls as the stent is delivered through and/or radially expanded within the blood vessel.

Prior methods of manufacturing stents from hypodermic tubing include coating the external surface of the tube with a photoresist material, optically exposing the etch pattern using a laser beam while translating and rotating the part and then chemically etching the desired slot pattern of the stent using conventional techniques. A description of this technique can be found in U.S. Pat. No. 5,421,955 to Lau, the complete disclosure of which is incorporated herein by reference. In other methods, laser cutting technology is used in conjunction with computer controlled stages to directly cut a pattern of slots in the wall of the hypodermic tubing to obtain the desired stent geometry. These chemical etching and laser cutting methods, however, produce stents in which the slots have rough surfaces with slag particles and other debris attached. In addition, these methods often produce sharp metallic edges or burrs which could rupture an angioplasty balloon or damage the anatomical lumen. Conventional deburring methods, such as bead blasting and tumbling with abrasive media generally cannot be used with stents because the stents are extremely small (on the order of 1.5 mm diameter) and fragile and, therefore, difficult to handle. In addition, in the case of abrasive media, the slots are too small for the medium to penetrate and abrade the edges and cut surfaces.

Currently used technology for deburring and polishing stents involves a process called electropolishing. Electropolishing is a bulk process for removing the sharp corners and edges as well as polishing the wall surfaces and cut surfaces of metallic stents. This technology comprises a reverse electroplating process in which stents are preferably supported by a conductive wire and submerged in a caustic liquid solution, such as a mixture of phosphoric and sulfuric acid. A cathode is also submerged into the electrolytic solution so that an electric potential can be established between the cathode and the anode. The electric potential removes metallic material from the stent to thereby polish the wall surfaces and round the edges of the stent.

Although electropolishing technology improves the macroscopic appearance of the stent surfaces, stents polished by this process suffer from a number of disadvantages. One disadvantage is that electropolishing is relatively ineffective in removing the upraised burrs, slag and debris from the cut edges of the stent. This means that to properly deburr and round off the edges, it is often necessary to remove as much as 0.025 mm from the exposed surfaces, including the inner and outer wall surfaces as well as the cut surfaces of the stent. Since the wall thickness of a finished stent is typically in the range of 0.075 mm to 0.1 mm and since the tubing material may originally be on the order of 0.125 mm to 0.15 mm in thickness, removing up to 40% of the material thickness makes it difficult to control the overall uniformity of the stent geometry.

Another disadvantage of having to remove up to 0.025 mm from all surfaces is that the resulting surface, while macroscopically smooth and shiny, becomes cratered and even pitted when viewed under the microscope. In the case, e.g., of type 316 stainless steel (a favored material in the manufacture of malleable stents), the surface on the inner cylindrical surface becomes more cratered than the outer cylindrical surfaces, and the cut surfaces become deeply pitted. As mentioned above, this may have profoundly damaging consequences for the thrombogenicity of the stent when implanted in an artery and exposed to the bloodstream.

For these and other reasons, it would be desirable to provide methods and apparatus for effectively deburring the edges and polishing the wall surfaces and cut surfaces of stents. These methods and apparatus should be capable of removing burrs and particles from the edges and the wall surfaces of the stent to provide a microscopically smooth surface. Furthermore, this deburring and polishing should be accomplished by removing a minimal amount of material from the wall surfaces. Additionally, the stent should be handled delicately without causing any structural damage or distortion during the polishing process.

2. Description of the Background Art

U.S. Pat. No. 5,421,955 to Lau describes a method for manufacturing a radially expansible stent by chemically

etching hypodermic tube, and then electropolishing the stent in an aqueous solution to polish the stent. U.S. Pat. Nos. 3,634,973 and 3,521,412 to McCarty and 5,367,833, 5,070,652, 4,936,057 and 3,819,343 to Rhoades describe methods and apparatus for abrading and deburring metal parts with an abradable medium, such as silicone putty loaded with very fine abrasive media, a process also known as abrasive flow machining. These methods comprise mounting the metal parts to be deburred and polished onto a machine and forcing the abradable medium over the surfaces of the metal parts to polish and debur the surfaces and edges.

SUMMARY OF THE INVENTION

The present invention provides methods and apparatus for deburring the edges and for polishing the surfaces of radially expansible lumenal prostheses, such as stents and grafts. The invention involves mounting a lumenal prosthesis onto a fixture and radially extruding an abrasive slurry through circumferential openings in the prosthesis in abrading contact with cut surfaces and edges surrounding these openings. The abrasive slurry can be selectively directed through the small openings and passages defined by the struts or beams of the stent to remove upraised slag and metallic particles, especially on the cut wall surfaces, thereby providing a microscopically smooth surface. In addition, the flow of the slurry can be effectively controlled so that the burrs and the stent edges are rounded with a minimum amount of surface material being removed from the wall surfaces of the stent.

Lumenal prostheses or stents typically comprise a cylindrical metallic, elongate body sized for delivery through an anatomical lumen and having first and second open ends and an inner lumen therebetween. Such stents typically have an outside diameter in the range of 1.5 mm to 5.0 mm and a length in the range of 8 mm to 30 mm. The elongate body of the stent comprises a plurality of strut or beam elements that define narrow slots and small openings when the stent has been manufactured out of hypodermic tubing. When the stent is radially expanded within an anatomical lumen, the narrow slots will expand to form a generally rhomboidal and/or serpentine body structure suitable for the formation of a scaffold for supporting an anatomical lumen. The method of the present invention includes mounting the stent as manufactured to a fixture or polishing apparatus so that at least a portion of the stent is positioned adjacent an interior wall of the apparatus to define a restrictive flow passage therebetween. A flowable abrasive media comprising abrasive grains dispersed in a pliable matrix forming a viscous slurry is then extruded through the restrictive flow passage to abrade or polish the portion of the stent.

To effectively debur the edges and polish the cut surfaces surrounding the small body openings in the stent, the abrasive slurry is introduced into the inner lumen of the stent and extruded radially outward through these openings over a relatively short longitudinal portion of the stent. Preferably, the slurry is introduced under pressure directly into the central portion of the inner lumen via one or two delivery tubes. The flow of the slurry may be reversed so that it is radially extruded inwardly through the openings and then discharged through the delivery tube(s). This reversal in the flow of the slurry through the small body openings of the stent will ensure more uniform deburring of both the inner and outer edges of the stent.

A portion of the slurry may also be extruded axially past the inner surfaces of the stent and the outer surface of the delivery tube(s) to remove material from the inner surfaces of the stent. The outer surfaces of the stent may also be polished by axially directing the abrasive slurry through restrictive passages between outer surfaces of the stent and a hole in the fixture surrounding the stent. The stent may be axially reciprocated and/or rotated within this hole so that the flowing slurry will come into abrading contact with substantially all of the edges and the wall surfaces of the stent. Preferably, however, the metallic hypodermic tubing will be polished both on its outer and inner surfaces before the stents are manufactured thus limiting the deburring and polishing operation of the finished stent mainly to the edges and newly cut surfaces of the stent. In this manner, the material removed from the stent will be in the range of 0.005 mm to 0.01 mm instead of about 0.025 mm, which is the amount of material currently being removed with electropolishing techniques. Furthermore, the surface roughness of stents polished by the electropolishing process will generally be greater than R_a=0.8 microns. On the other hand, stents polished by means of the present invention may result in surfaces having a surface roughness of less than R_a=0.4 microns. Polishing the outer surface of the tube is best accomplished by conventional centerless grinding while polishing of the inside of the tube is best accomplished by abrasive flow machining.

The flowable abrasive material preferably comprises a pliable semisolid carrier and a concentration of abrasive grains. The carrier or media holds the abrasive particles in suspension and transports them through the restrictive passages defined by the stent. The abrasive particles remove burrs from edges and round edges and corners, as well as smoothing and polishing metal on the wall surfaces of the stent. The preferred media for use in the present invention are polyborosiloxanes, which may be plasticized, usually with silicone fluids, to a suitable low shear viscosity to allow passage of the abrasive slurry through narrow slots with minimal pressure drop. The medium is filled with an appropriate charge of suitable abrasive grains, such as silica, alumina, carborundum, garnet, tungsten carbide, silicon carbide, diamond, boronic carbide and the like.

The apparatus of the present invention comprises a base defining a chamber with an interior wall sized to receive at least a portion of the stent and a mount for holding the stent so that it is at least partially disposed within the chamber. A fluid conduit has an inlet for receiving an abrasive slurry and a passage for delivering the abrasive slurry into restrictive passages defined by the outer surfaces and the interior lumenal wall of the stent. The apparatus further includes a pair of receiving/delivery tubes positioned through the open ends of the tubular extensions of the stent for receiving or delivering the abrasive slurry from or into an interior portion of the stent. The tubes are sized and positioned to allow the slurry to primarily radially extrude through the slots or openings in the stent. Secondarily, the slurry will flow between the outer surface of the tubes and the lumen or the inner surfaces of the stent and between the outer surfaces of the stent and the surrounding chamber walls of the base.

In a specific configuration, lateral extensions of the lumenal prosthesis are mounted to a pair of mounting arms so that the stent extends through a hole in the base. The hole defines an annular gap between the outer surface of the inlet/outlet tubes and the interior walls of the hole. The mounting arms are coupled to a drive for reciprocating and/or rotating the prosthesis within the hole during the abrading process. The receiving/delivery tubes remain fixed relative to the base during reciprocation of the prosthesis.

Other features and advantages of the invention will appear from the following description in which the preferred embodiment has been set forth in detail in conjunction with the accompanying drawings.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a representative prior art stent in a collapsed configuration;

FIG. 2 is a partial detailed view of one of the circumferential openings in the stent of FIG. 1, taken along line 2—2, illustrating the rough edges and rough cut surfaces surrounding the opening;

FIG. 3 is a perspective view of the stent of FIG. 1 connected to a pair of tubular extensions;

FIG. 4 is a schematic representation of a system for polishing a lumenal prosthesis;

FIG. 5 is a side cross-sectional view of the stent and tubular extensions of FIG. 3 mounted to the apparatus of the polishing system of FIG. 4;

FIG. 6 is a partial isometric cross section of a stent in the apparatus of the polishing system of FIG. 4, illustrating the flow of abrasive slurry;

FIG. 7 is a partial isometric cross section of a stent in the apparatus of an alternative polishing system illustrating the flow of abrasive slurry; and

FIG. 8 is a representation of a solid rod supporting a series of stents separated by spacers for use with the alternative polishing system of FIG. 7.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

FIGS. 1-3 illustrate a representative intravascular stent structure adapted for delivery into a blood vessel or other anatomical lumen. It should be understood, however, that although a particular stent structure is described below and shown in FIGS. 1-3, the present invention is not intended to be limited to this structure. That is, the method and apparatus of the present invention can be utilized to deburr and polish a variety of stents commonly used in this art. For example, representative conventional stent structures made from metallic tubular materials that are currently marketed as implants for coronary, peripheral, biliary and other vessels include the Palmaz-Schatz™ balloon expandable stent, manufactured by Johnson and Johnson Interventional Systems, Co. and made from malleable stainless steel hypodermic tubing; and the Memotherm® stent, manufactured by Angiomed, a division of C. R. Bard, Inc., manufactured out of nitinol tubing which takes advantage of a shape memory effect to reach its deployed size. In both of these examples, a series of offset slots in the surface of the collapsed stent are deformed when the stent is deployed into its expanded configuration.

In a typical embodiment, a stent structure 2 is preferably constructed of a thin walled stainless steel hypodermic tubing having a wall thickness in the range of 0.125 mm to 0.15 mm and having a relatively small collapsed diameter in the range of 1.5 mm to 5.0 mm to fit within small tortuous anatomical lumens within the body. In FIG. 1, stent 2 is shown in a radially collapsed, (i.e., as manufactured configuration) and in the example shown, comprises a hollow elongate body 4 having two radially expansible body segments 6 joined by one axial articulation tab 8. The body segments each include a number of slots forming box structures 10 which are circumferentially joined by tabs 12. It will be appreciated that the box structures 10, comprised of beam members 18 and 20, will radially expand as the stent is expanded in a conventional manner, e.g., by application of an internal balloon force where the stent is made from a malleable material, such as stainless steel. More detailed descriptions of malleable stents are provided in U.S. Pat. Nos. 5,102,417 and 4,776,337 to Palmaz and U.S. Pat. No. 5,195,984 to Schatz. A more advanced stent structure incorporating multiple articulations along its length is provided in commonly assigned, co-pending application Ser. No. 08/463,166 to Klein, filed on Jun. 5, 1995, the complete disclosure of which is incorporated herein by reference.

In addition to plastically deformable stents, the present invention will be suitable for deburring and polishing self-expanding stents formed from resilient materials, such as shape memory alloys, e.g., nitinol. Such stents will be formed so that they are expanded at room and/or body temperature and are delivered in a constrained and/or unconstrained, cooled condition. Once in position in the vasculature or other body lumen, the stent will radially expand due to the resiliency and/or shape memory of its own structure. Such stents are described, for example, in WO 94/17754 (the complete disclosure of which is incorporated herein by reference), where a nitinol stent is machined from a nitinol tube.

As shown in FIG. 1, elongate body 4 of stent structure 2 includes open ends 22, 24 for receiving an expandable balloon on the distal end of a catheter (not shown) within an internal lumen 26 in body 4. All of the individual elements of stent 2 (i.e., box structures 10, comprised of beam members 18, 20, tabs 12 and tab 8) define inner and outer wall surfaces 28, 29 and a plurality of longitudinal openings 30 between the elements. As best shown in FIG. 2, circumferential openings 30 define side or cut surfaces 32 surrounding openings 30 and inner and outer cut edges 34, 36 between the inner and outer surfaces 28, 29 of the stent elements, respectively. These edges and surfaces are shown as cut, for example, by a laser beam, including slag at the edges 34 and 36 (not shown) and rough surfaces 32. The inner surfaces and cut edges of the completed stent will contact the expansion balloon and will be exposed to the blood stream. In addition, the outer surfaces will contact the blood vessel wall and the side surfaces will be exposed to the blood stream. Therefore, all of the completed stent surfaces should be as smooth and rounded as possible to avoid rupture of the balloon, damage to the vessel wall and/or the creation of foci for platelet aggregation therein.

FIG. 3 illustrates the exemplary stent structure 2 of FIG. 1 having a pair of tubular extensions 40, 42 (shown shortened for convenience). Tubular extensions 40 are provided to facilitate the handling of the delicate stent structure 2 after the slots 30 have been cut, and to enable the fixturing of the stent configuration of FIG. 3 within the polishing apparatus of the present invention (described below). Tubular extensions 40, 42 are attached to the elongate body 4 typically by three circumferentially distributed tabs 38, which are severed and smoothed out after completion of the deburring and polishing operation and after an inspection process. Tubular extensions 40, 42 are hollow elongate members having a diameter substantially equal to the diameter of stent 2 and usually being part of the tubing that the stent was manufactured from.

FIG. 4 illustrates a hydraulic system 50 for polishing a lumenal prosthesis, such as the stent 2 described above and illustrated in FIGS. 1-3. System 50 comprises a source of abrasive slurry 52 fluidly coupled to a polishing apparatus 58 for mounting stent 2 thereto and primarily to deburr the edges and polish the cut surfaces of stent 2 with the abrasive slurry. System 50 may also secondarily abrade and polish the outer and inner surfaces of stent 2. System 50 includes a pump 54 to pressurize the abrasive slurry and propel it alternatively through fluid conduits 60 or 62, delivering the slurry to polishing apparatus or fixture 58. Hydraulic system

50 will preferably comprise a closed loop pumping system including a pump 54 in the form of a large capacity, fully controlled, double acting, positive displacement pump. The slurry source 52 is connected to pump 54 via conduit 56 and valve 66 and mainly serves to replace spent slurry or replenish slurry lost in the process due to leakage in the system (since the slurry can be repeatedly recirculated, as discussed below). On a first stroke, abrasive slurry is discharged through conduit 60 via branches 64 and 66 into polishing apparatus 58 through delivery tubes 102 and 104 and, after passing through, is returned to the pump 54 out of port 86 through conduit 62. (following the direction of the broken arrows). On a second stroke, the abrasive slurry may be discharged from pump 54 through conduit 62 following a reverse path through the polishing assembly, as indicated by the solid arrows.

It should be noted that the invention is not limited to any one system for delivering the abrasive slurry to polishing apparatus 58. A variety of mechanisms for forcing a viscous fluid through small restrictive passages with large pressure drops can be used, such as reciprocating single or double acting piston pumps, rotating screws or the like.

As shown in FIG. 5 and partially in FIG. 6, polishing apparatus 58 comprises a base 72 and a cylindrical body 74 mounted to an upward extension 100 of base 72 forming a cylindrical housing 84 for body 74. Body 74 defines a cylindrical hole 76 (best seen in FIG. 6) for receiving at least a portion of stent 2. Hole 76 preferably has a length that is less than the length of stent 2. One end of cylindrical housing 84 includes an opening 82 opposite base 72 for receiving a threaded fitting 86. As shown in FIG. 5, fitting 86 threadably couples fluid line 62 to cylindrical housing 84, and therethrough to body 74 so that the abrasive slurry can be delivered to (or discharged from) hole 76 through conduit 62. Polishing apparatus 58 further includes a conduit assembly for delivering the abrasive slurry into inner lumen 26 of stent 2. Preferably, the conduit assembly includes first and second delivery tubes 102, 104 extending through open ends 22, 24 of stent 2 into the central portion of inner lumen 26, as shown in FIG. 5. Delivery tubes 102, 104 have inlets/outlets 106, 108 coupled to fluid conduit branches 64, 66 and outlets/inlets 110, 112 positioned opposite each other within inner lumen 26 for delivering the abrasive slurry therein. Delivery tubes 102, 104 are supported by a pair of stands 116, 118 suitably mounted to base 72. Tubes 102, 104 are preferably removably attached to stands 116, 118 to facilitate the mounting and subsequent removal of stent 2 from the polishing apparatus.

As best shown in FIG. 6, cylindrical body 74 of polishing apparatus 58 further defines a narrow disk shaped gap 77 surrounded by a tapered annular chamber 80 (FIG. 5) in communication with hole 76. In a first operation, defined by flow following the broken arrows in FIG. 4, slurry flows through tubes 102, 104 into inner lumen 26 of prosthesis 2, where it is forced radially outward through openings 30 into gap 77, as indicated by the arrows in FIG. 6. Gap 77 preferably completely surrounds the prosthesis to ensure that the slurry will extrude through the openings 30 around the entire circumference of the prosthesis. Of course, it should be noted that the invention is not limited to this configuration and the polishing apparatus can include a chamber that does not fully surround the stent, together with means for rotating the stent.

Polishing apparatus 58 primarily abrades the edges 34, 36 and cut surfaces 32 of openings 30. The inner and outer surfaces 28, 29 are preferably polished prior to this process in, for example, a similar process that abrades these surfaces before the openings 30 are cut into the prosthesis body. However, polishing apparatus 58 may be utilized to secondarily polish inner and outer surfaces 28, 29 while the cut surfaces and edges are being polished. To that end, hole 76 has a diameter slightly greater than the diameter of stent 2 to define an annular restrictive passage 78 between body 74 and the outer surfaces 29 of stent 2 when the stent is mounted therein (as best shown in FIG. 5). Restrictive passage 78 is preferably sized so as to allow a small portion of the abrasive slurry to flow therethrough in abrading contact with the outer surfaces 29 of stent 2.

Also, as shown in FIG. 5, delivery tubes 102, 104 are preferably sized to define an annular gap or restrictive passage 120 between the outer surface of tubes 102, 104 and the inner surfaces 28 of stent 2. This restrictive passage should be small enough so that annular passage 120 offers substantially more resistance to the abrasive flow than the circumferential openings 30 in the body of stent 2. This will allow a small portion of the abrasive slurry to flow through annular passage 120 to thereby polish inner surfaces 28 of the stent. The size of annular passages 78 and 120 will be determined mainly by the consistency of the abrasive slurry and the axial lengths of the respective annular passages, and will further be constrained so that a substantial portion of the abrasive slurry will flow radially outward through openings 30 after it has been delivered into the inner lumen 26 of the prosthesis 2.

As shown in FIG. 5, mounting apparatus 58 further includes a movable frame 92 for reciprocating stent 2 within hole 76 so that the entire length of stent 2 may be disposed within hole 76 during the course of the abrasive operation. With this configuration, the abrasive slurry will be in abrading contact with all of the cut surfaces 32 and edges 34, 36 of openings 30 as it is radially extruded from the inner lumen of stent 2 into chamber 77 through openings 30 over a limited axial length of the stent 2. In a specific embodiment, frame 92 includes a base portion 94 movably coupled to base 72 and having first and second mounting arms 96, 98 extending upward from base portion 94 on opposite sides of body 74, as shown in FIG. 5. Mounting arms 96, 98 each have an opening for receiving tubular extensions 40, 42 (see FIG. 3), which can be suitably attached to arms 96, 98 by conventional fastening means, such as a chuck or a collet mechanism. Preferably, frame 92 is coupled to base 72 by a linear guidance mechanism and driven through a lead screw powered by a microprocessor controlled electrical motor (not shown). The edges and cut surfaces of a cylindrical portion of the stent will all be polished simultaneously (the portion centered with disk shaped gap 77). To polish all of the surfaces on the entire length of the stent, the stent will be reciprocated longitudinally from end to end.

The preferred abrasive slurry of the present invention comprises a pliable semisolid carrier having a concentration of abrasive grains. The carrier or media preferably has sufficient body at high pressure and low velocity to provide backing for the abrasive particles so that the abrasive particles are pressed against the surface to be treated with sufficient force to obtain the desired deburring and polishing result. The media will preferably be of a suitably low viscosity which is generally appropriate for deburring edges and for polishing small passages. The preferred carrier or media for use in the present invention are polyborosiloxanes, which may be plasticized, usually with silicone fluids, to a suitably low shear viscosity. One suitable medium is silicone putty, i.e., borosiloxane, of a suitable grade. A more thorough discussion of abrasive slurries appropriate for the present invention can be found in U.S.

Pat. Nos. 3,634,973 and 3,521,412 to McCarty and 5,367,833, 5,070,652, 4,936,057 and 3,819,343 to Rhoades, the full disclosures of which are incorporated herein by reference.

The media is filled with an appropriate charge of a suitable abrasive grain, such as silica, alumina, carborundum, garnet, tungsten carbide, silicon carbide, diamond, boron carbide and the like. Normally, the content of abrasive material per part of putty material will be from about two parts to about fifteen parts by weight. Typically, abrasive particle size ranges from 0.005 mm to 1.5 mm. Larger size abrasive particles effect deeper cuts per grain. It is also possible to employ abrasive flow machining or polishing in multiple steps, with the initial stage being conducted with an abrasive medium containing larger size abrasive particles and subsequent abrasive flow operations being conducted with abrasive media containing finer abrasive particles.

The method for polishing the surfaces **28**, **29**, **32** and deburring and rounding edges **34**, **36** of stent **2** will now be described with reference to FIGS. **1–6**. The stent is in a collapsed configuration, as shown in FIG. **1**, but includes tubular extensions **40**, **42** (FIG. **3**) for fixturing within apparatus **58**, as shown in FIG. **3**. Stent **2** is then positioned within hole **76** of cylindrical body **74** and tubular extensions **40**, **42** are mounted to arms **96**, **98** of frame **92** (see FIGS. **5** and **6**). Delivery tubes **102**, **104** are then introduced through the stent internal lumen **26**, leaving a longitudinal gap between ends **110** and **112**, centered with and slightly larger than gap **77** in body **74**.

As shown in FIGS. **5** and **6**, in a first operation mode, the abrasive slurry flows through delivery tubes **102**, **104** and into the exposed gap of inner lumen **26** of stent **2**. Once the abrasive slurry has substantially filled the space between the opposing outlets **110**, **112** of delivery tubes **102**, **104**, it will extrude through circumferential openings **30** in the body **4** of stent **2** in abrading contact with cut surfaces **32** and edges **34**, **36** (FIG. **2**). A portion of the abrasive slurry may also extrude through restrictive passages **120** between inner surfaces **28** of stent **2** and the outer surface of delivery tubes **102**, **104** to thereby abrade the inner surfaces **28** of the stent.

As shown in FIG. **5**, the portion of abrasive slurry that passes through restrictive passages **120** inside of stent **2** and tubular extensions **40**, **42**, will be suitably discharged through the open ends of the tubular extensions. The portion of slurry that extrudes through openings **30** will pass radially through gap **77** (FIG. **6**) to be channelled via chamber **88** into fitting **86** and back to pump **54** through conduit **62**. A portion of this slurry will also flow through restrictive passages **78** between the inner surface of hole **76** and the outer surfaces **29** of stent **2** to thereby abrade the outer surfaces **29** of the stent. To expose the remaining openings **30** with surfaces **32** and edges **34**, **36** of stent to the flow of abrasive slurry, frame **92**, holding the stent with tubular extensions **40**, **42** through arms **96**, **98**, must be traversed relative to stationary frame **72** until the entire length of stent **2** has been processed.

To fully polish both the outer and inner edges **34**, **36** of the openings **30** in stent **2**, the above described flow process may be reversed in a second operation mode, wherein the abrasive slurry enters apparatus **58** through conduit **62** and exits through tubes **102**, **104**. In this mode, the traversing of the frame **92** relative to stationary frame **72** is repeated as in the first operation mode until stent **2** is fully and uniformly deburred and polished.

FIG. **7** illustrates an alternative embodiment that may be suitable for polishing a large number of stents in a production mode. In this embodiment, body **74** defines a disk shaped gap **77** and an inner hole **76** for receiving the stent, as described above. Inlet/outlet tube **108** is fixedly located relative to body **74**. Polishing apparatus **58** further includes a solid rod **120** supported by a suitable-stand (not shown) and extending through hole **76** of body **74**. As shown in FIG. **7**, rod **120** replaces inlet tube **106** of FIGS. **4** and **5** and is sized to fit within prosthesis **2** and to extend through body **74** with end **114** approximately at the position of tube end **110** of the earlier embodiment, leaving a longitudinal gap between the ends **114**, **112**, centered with and slightly larger than gap **77** in body **74**. In this embodiment, the slurry flows into inner lumen **26** only from inlet/outlet tube **108** and radially outward/inward through openings **30** into gap **77**. In a first operation mode, the flow of abrasive slurry is illustrated in FIG. **7** by the arrows.

FIG. **8** illustrates rod **120** having a train **250** of two stents **2**, **3** and three separate spacers **214**, **216**, **218** mounted thereon (shown spaced apart for clarity). In this alternative configuration, stents **2**, **3** need not be provided with tubular extensions **40**, **42** since the stent is no longer mounted on a frame structure **92**. Spacers **214**, **216**, **218** have substantially equivalent inner and outer diameters as stents **2**, **3** and are provided with multiple protrusions **220** extending axially to allow the abrasive slurry to also deburr and polish the ends of stents **2**, **3**. Of course, it should be clearly understood that while only two stents and three spacers are shown, a larger number of stents interspaced by spacers may be mounted on a longer rod **120**. In fact, this embodiment facilitates the polishing of a large number of stents in a batch process.

In a modified method from that described in the previous embodiment, a rod **120** having a number of completed stents with no tubular extensions, separated by spacers is installed as shown in the exemplary modified apparatus of FIG. **7** (note that only one stent **2** and two spacers **214**, **216** are shown in FIG. **7**). With rod **120** stationary with respect to the frame (not shown), the train **250** of stents and spacers may be advanced over rod **120** in a sliding relationship, to expose openings **30** in new sections of stent **2** to the flow of abrasive slurry within the open section of lumen **26**. When one stent has been completely traversed across gap **77** in FIG. **7**, for example from left to right, a spacer followed by a second stent may be equally traversed from left to right until all stents on rod **120** have been treated.

In a preferred method, once a suitable abrasive slurry has been selected and all gaps in the apparatus have been optimized for a particular type of stent, a rod **120** with a train **250** of stents and spacers will be mounted as described above. In a first operating mode, the abrasive slurry is propelled into tube **108** in the direction shown by the arrow in FIG. **7**, and will exit radially through gap **77** in body **74** after passing through the exposed portion of the stent. The train **250** of stents and spacers will then be advanced over rod **120**, for example, from left to right, until all stents have been treated and the train is in its full rightward position. In a second operating mode, the direction of flow of the abrasive slurry will be reversed from that shown by the arrows in FIG. **7** and the train of stents will be advanced from right to left until it is in its full leftward position. Preferably, upon completion of the above cycle, stents in the train will have been suitably deburred and polished and ready for chemical passivation and final inspection. The process can then be repeated with a new train of stents and spacers mounted on another rod. This embodiment facilitates the polishing of a large number of stents in a batch process.

Although the foregoing invention has been described in detail for purposes of clarity of understanding, it will be

obvious that certain modifications may be practiced within the scope of the appended claims. For example, the polishing system may further include a control system for monitoring and controlling process parameters, such as media temperature, viscosity, wear and the flow rate, as well as the advance velocities of the stents across the gap.

What is claimed is:

1. A method for deburring and polishing a radially expansible lumenal prosthesis having a hollow elongate body with an inner lumen, wherein said body comprises a plurality of elongated longitudinal openings circumferentially spaced-apart about the body, the method comprising:

mounting the lumenal prosthesis within a chamber such that openings spaced around a circumference of the elongate body are fluidly coupled to the chamber; and

radially extruding a flowable abrasive material through the openings around the circumference of the elongate body in abrading contact with cut surfaces and edges surrounding the openings, wherein all abrasive material flows from the lumen radially outwardly through the openings to the exterior of the prosthesis or from the exterior of the prosthesis radially inwardly to the lumen.

2. The method of claim 1 wherein the radially extruding step comprises introducing the flowable abrasive material into the inner lumen of the prosthesis body and directing the flowable abrasive material radially outward through the openings in the prosthesis body.

3. The method of claim 1 wherein the radially extruding step comprises:

mounting the lumenal prosthesis to a fixture; and

introducing the flowable abrasive material into a gap of the fixture in communication with the prosthesis body and directing the flowable abrasive material radially inward through the openings in the prosthesis body.

4. The method of claim 2 wherein the radially extruding step is carried out by positioning a hollow tube through an open end of the prosthesis body and a solid rod through an opposite open end of the prosthesis and delivering the flowable abrasive material under pressure through the hollow tube into the inner lumen of the prosthesis body so that the flowable abrasive material is forced radially outward through the openings in the prosthesis body.

5. The method of claim 2 wherein the radially extruding step is carried out by positioning a hollow tube through an open end of the prosthesis body and a solid rod through an opposite open end of the prosthesis and delivering the flowable abrasive material under pressure radially inward through the openings in the prosthesis body into the inner lumen of the prosthesis body and through the hollow tube.

6. The method of claim 2 wherein the radially extruding step is carried out by positioning a first hollow tube through an open end of the prosthesis body and a second hollow tube through a second open end of the prosthesis body opposite the first open end and delivering the flowable abrasive material under pressure through the first and second hollow tubes into the inner lumen of the prosthesis body such that the flowable abrasive material is forced radially outward through the openings in the prosthesis body.

7. The method of claim 2 wherein the radially extruding step is carried out by positioning a first hollow tube through a first open end of the prosthesis body and a second hollow tube through a second open end of the prosthesis body opposite the first open end and delivering the flowable abrasive material under pressure radially inward through the openings in the prosthesis body into the inner lumen and through the first and second hollow tubes.

8. A method for deburring and polishing a radially expansible lumenal prosthesis having a hollow elongate body, the method comprising:

mounting the lumenal prosthesis adjacent a fluid conduit;

radially extruding a flowable abrasive material through the fluid conduit and through openings on a circumference of the elongate body in abrading contact with cut surfaces and edges surrounding the openings;

providing hollow, tubular extensions to first and second ends of the prosthesis; and

mounting the tubular extensions to a fixture.

9. The method of claim 8 wherein the mounting step further comprises mounting each of the tubular extensions within a frame movably coupled to the fixture such that at least a portion of the prosthesis body extends through a hole in the fixture.

10. The method of claim 9 wherein the fixture defines an annular chamber in communication with the hole, the method further comprising radially extruding the flowable abrasive material through openings circumferentially spaced about the prosthesis body into the annular chamber.

11. The method of claim 8 wherein the radially extruding step further comprises reciprocating the tubular extensions in an axial direction relative to the fixture such that the cut surfaces and edges surrounding substantially all of the circumferential openings in the prosthesis body will be in abrading contact with the flowable abrasive material.

12. The method of claim 1 wherein the extruding step further comprises:

mounting the lumenal prosthesis within a hole of a fixture;

delivering the flowable abrasive material through a passage in communication with the hole; and

extruding a portion of the flowable abrasive material through a passage defined by outer surfaces of the prosthesis body and an inner surface of the hole to abrade said outer surfaces.

13. The method of claim 1 wherein the extruding step further comprises:

positioning first and second tubes through first and second open ends of the lumenal prosthesis;

delivering the flowable abrasive material into the inner lumen of the prosthesis between open ends of the first and second tubes; and

extruding a portion of the flowable abrasive material through a passage defined by an outer surface of the first and second tubes and inner surfaces of the prosthesis body to abrade said inner surfaces.

14. The method of claim 1 further comprising:

providing a train of prostheses spaced apart by spacers and disposed along a solid rod;

guiding a first prosthesis in the train of prostheses in a longitudinal direction over the solid rod so that at least a portion of the first prosthesis is extends through an annular chamber within a fixture;

radially extruding the flowable abrasive material through the openings in the circumference of the first prosthesis;

guiding the first prosthesis in the longitudinal direction out of the fixture; and

guiding a second prosthesis in the train of prostheses over the solid rod in the longitudinal direction so that at least a portion of the second prosthesis extends through the annular chamber within the fixture.

15. The method of claim 14 wherein the radially extruding step is carried out by positioning a hollow tube through an

open end of the prostheses opposite the solid rod and delivering the flowable abrasive material under pressure through the hollow tube into the inner lumen of the prosthesis body so that the flowable abrasive material is forced radially outward through the openings in the prosthesis body.

16. The method of claim 15 wherein the train of prostheses are advanced along the solid rod toward the hollow tube as the flowable abrasive material is extruded radially outward through said openings in the prostheses.

17. The method of claim 14 wherein the radially extruding step is carried out by positioning a hollow tube through an open end of the prostheses opposite the solid rod and radially extruding the flowable abrasive material radially inward through the openings in the circumference of the prostheses and into the hollow tube.

18. The method of claim 17 wherein the train of prostheses are advanced along the solid rod away from the hollow tube as the flowable abrasive material is extruded radially inward through said openings in the prostheses.

19. The method of claim 14 wherein the first solid rod and the first train of prostheses are replaced by a second solid rod and a second train of prostheses after the openings in the prostheses of the first train of prostheses have been polished and deburred.

20. The method of claim 1 wherein the flowable abrasive material comprises abrasive particles suspended in a semisolid carrier.

21. The method of claim 20 wherein the abrasive particles are selected from the group consisting of silica, alumina, carborundum, garnet, tungsten carbide, silicon carbide and diamond.

22. The method of claim 20 wherein the semisolid carrier comprises a polyborosiloxane.

23. An apparatus for deburring and polishing a radially expansible lumenal prosthesis having an elongate body sized for delivery through an anatomical lumen and having an inner lumen, wherein said body comprises a plurality of elongated longitudinal openings circumferentially spaced-apart about the body, the apparatus comprising:

a fixture defining a chamber for receiving at least a portion of the lumenal prosthesis; and

a fluid hydraulic system in communication with the chamber or radially extruding the flowable abrasive material through openings spaced around a circumference of the prosthesis body in abrading contact with cut surfaces and edges surrounding the openings, wherein the system directs all flow of abrasive material from the lumen radially outwardly through the openings to the exterior of the prosthesis or from the exterior of the prosthesis radially inwardly to the lumen.

24. The apparatus of claim 23 wherein the fixture defines a hole sized for receiving the lumenal prosthesis and an annular chamber circumscribing a portion of the hole, the fluid hydraulic system being in communication with the annular chamber for delivering the flowable abrasive material into the annular chamber and radially inward through the openings and into the inner lumen of the prosthesis.

25. An apparatus for deburring and polishing a radially expansible lumenal prosthesis having an elongate body sized for delivery through an anatomical lumen, the apparatus comprising:

a fixture defining a chamber for receiving at least a portion of the lumenal prosthesis; and

a fluid conduit in communication with the chamber for radially extruding the flowable abrasive material through opening in the circumference of the prosthesis body in abrading contact with cut surfaces and edges surrounding the openings;

wherein the fluid conduit is a hollow tube sized for positioning through an open end of the lumenal prosthesis into the inner lumen, the hollow tube having an inlet adapted for receiving a flowable abrasive material and an outlet in communication with the inner lumen for delivering the flowable abrasive material under pressure into the inner lumen.

26. The apparatus of claim 25 further comprising an elongate flow restrictor sized for introduction through a second open end of the lumenal prosthesis opposite the first open end for inhibiting flow through said second open end so that the flowable abrasive material delivered into the inner lumen is radially extruded through the openings in the prosthesis body.

27. The apparatus of claim 25 further comprising a second hollow tube sized for introduction through a second open end of the lumenal prosthesis opposite the first open end, the second tube having an inlet adapted for receiving a flowable abrasive material and an outlet in communication with the inner lumen for delivering the flowable abrasive material under pressure into the inner lumen.

28. The apparatus of claim 27 wherein the tubes are sized to define an annular gap between the tubes and inner surfaces of the prosthesis such that a portion of the flowable abrasive material flows through the annular gap in abrading contact with the inner surfaces of the prosthesis.

29. The apparatus of claim 28 wherein the annular gap offers a greater resistance to flow than the openings in the prosthesis body so that a substantial portion of the flowable abrasive material is extruded through the openings in abrading contact with the cut surfaces and edges surrounding said openings.

30. The apparatus of claim 24 wherein the hole in the fixture is sized to define a restrictive passage between outer surfaces of the lumenal prosthesis and an inner surface of the hole, the restrictive passage offering a greater resistance to flow than the openings in the circumference of the prosthesis body such that the flowable abrasive material delivered into the annular chamber primarily flows through the circumferential openings of the prothesis body and secondarily flows through the restrictive passage in abrading contact with the outer surfaces of the prosthesis body.

31. An apparatus for deburring and polishing a radially expansible lumenal prosthesis having an elongate body sized for delivery through an anatomical lumen, the apparatus comprising:

a fixture defining a chamber for receiving at least a portion of the lumenal prosthesis; and

a fluid conduit in communication with the chamber for radially extruding the flowable abrasive material through openings in the circumference of the prosthesis body in abrading contact with cut surfaces and edges surrounding the openings;

wherein the fixture comprises a base and a mount coupled to the base for holding the lumenal prosthesis such that said portion of the lumenal prosthesis is disposed within the chamber, the mount comprising first and second mounting arms extending from the base on opposite sides of the chamber, the mounting arms each being adapted to hold an end portion of the prosthesis body.

32. The apparatus of claim 31 wherein the mounting arms are movably coupled to the base, the apparatus further comprising a drive for axially reciprocating the prosthesis body relative to the hole.

33. The apparatus of claim 26 wherein the elongate flow restrictor is a guide rod for supporting a train of lumenal prostheses longitudinally spaced apart by spacers.

34. The apparatus of claim 33 further comprising means for axially translating the train of lumenal prostheses along the guide rod.

35. A system for deburring and polishing a radially expansible lumenal prosthesis sized for delivery through an anatomical lumen and having an elongate, hollow body defining an inner lumen, the apparatus comprising:

a supply of flowable abrasive material;

a polishing assembly defining a chamber for holding at least a portion of the lumenal prosthesis within the chamber;

a fluid conduit having an inlet in communication with the supply of flowable abrasive material and an outlet in communication with the chamber, wherein said body comprises a plurality of elongated longitudinal openings circumferentially spaced-apart about the body; and

a pump for delivering the abrasive material under pressure through the fluid conduit and radially forcing the abrasive material through openings spaced around a circumference of the lumenal prosthesis in abrading contact with cut surfaces and edges surrounding the openings, wherein the system directs all flow of abrasive material from the lumen radially outwardly through the openings to the exterior of the prosthesis or from the exterior of the prosthesis radially inwardly to the lumen.

36. The system of claim 35 wherein the flowable abrasive material comprises abrasive particles suspended in a semi-solid carrier.

37. The apparatus of claim 36 wherein the abrasive particles are selected from the group consisting of silica, alumina, carborundum, garnet, tungsten carbide, silicon carbide and diamond.

38. The method of claim 36 wherein the semisolid carrier comprises a polyborosiloxane.

39. The method of claim 1 wherein the chamber is an annulus completely surrounding an axial Section of the elongate body, the method comprising directing the flowable abrasive material between the inner lumen of the prosthesis and the annulus through openings spaced around the entire circumference of the axial section.

40. The method of claim 39 further comprising;

moving the prosthesis relative to the annulus such that the annulus surrounds a second axial section of the prothesis; and

radially extruding a flowable abrasive material through openings in the second axial section of the prothesis between the annulus and the inner lumen of the prosthesis in abrading contact with cut surfaces and edges surrounding the openings.

41. The method of claim 1 wherein the elongate body has first and second opposing open ends, the method further comprising introducing the flowable abrasive material through the first and second open ends into the inner lumen of the elongate body and preferentially directing the flowable abrasive material radially outward through the openings in the elongate body.

42. The method of claim 1 wherein the elongate body has first and second opposing open ends, the method further comprising introducing the flowable abrasive material into the chamber around the elongate body and preferentially directing the flowable abrasive material radially inward through the openings into the inner lumen and through the first and second open ends of the prosthesis.

43. The method of claim 1 wherein the elongate body has first and second opposing open ends, the method further comprising introducing the flowable abrasive material through the first open end into the inner lumen of the elongate body and increasing a flow resistance through the second open end such that the flowable abrasive material preferentially flows radially outward through the openings in the elongate body to the chamber.

44. The method of claim 1 wherein the elongate body has first and second opposing open ends, the method further comprising introducing the flowable abrasive material into the chamber around the elongate body and preferentially directing the flowable abrasive material radially inward through the openings into the inner lumen and through the first open end of the prosthesis.

45. The apparatus of claim 23 wherein the chamber is an annulus sized to completely surround an axial section of the elongate body such that the flowable abrasive material may be directed through openings spaced around the entire circumference of the axial section.

46. The apparatus of 45 further comprising a drive for moving the prosthesis relative to the annular chamber such that the annulus surrounds a second axial section of the prosthesis.

47. The apparatus of claim 23 wherein the prosthesis has first and second opposing open ends, the apparatus further comprising a fluid conduit coupling the fluid hydraulic system with the first open end of the prosthesis and a fluid blocking element adapted for positioning adjacent to or within the second open end of the prosthesis for introducing the flowable abrasive material through the first open end into the inner lumen of the elongate body and preferentially directing the flowable abrasive material radially outward through the openings in the elongate body.

48. The apparatus of claim 23 wherein the prothesis has first and second opposing open ends, the apparatus further comprising a fluid conduit coupling the fluid hydraulic chamber with the annulus for introducing the flowable abrasive material into the annulus around the elongate body and directing the flowable abrasive material radially inward through the openings into the inner lumen, the apparatus further comprising a fluid blocking element adapted for positioning adjacent to or within the second open end of the prosthesis for preferentially directing the abrasive material through the first open end.

49. The apparatus of claim 23 wherein the prosthesis has first and second opposing open ends, the apparatus further comprising one or more fluid conduits coupling the fluid hydraulic system with the first and second open ends of the prosthesis for introducing the flowable abrasive material into the inner lumen of the elongate body and preferentially directing the flowable abrasive material radially outward through the openings in the elongate body.

50. The apparatus of claim 24 further comprising first and second fluid conduits coupled to first and second open ends of the prosthesis for preferentially directing the abrasive material from the inner lumen through the first and second open ends into the first and second fluid conduits.

* * * * *

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United States Patent [19]

Frantzen

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[45] Date of Patent: May 5, 1998

[54] **METHOD FOR POLISHING SURGICAL STENTS**

[75] Inventor: **John J. Frantzen**, Copperopolis, Calif.

[73] Assignee: **Global Therapeutics, Inc.**, Broomfield, Colo.

[21] Appl. No.: **870,962**

[22] Filed: **Jun. 6, 1997**

[51] **Int. Cl.**[6] **A61F 2/04**

[52] **U.S. Cl.** **600/36**; 623/1; 623/901; 451/36; 451/40; 451/89

[58] **Field of Search** 623/1, 12, 901; 606/198; 600/36; 451/36, 40, 89

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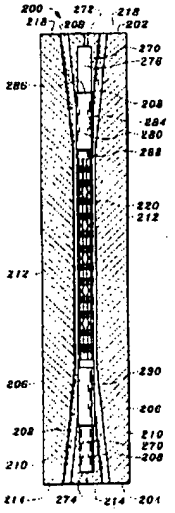
Primary Examiner—Paul B. Prebilic
Attorney, Agent, or Firm—Bradley P. Heisler

[57] **ABSTRACT**

A method for polishing radially expandable surgical stents is disclosed where fluid abrasive media M flows over surfaces of the stent **10** causing the surfaces of the stent **10** to be polished and streamlined. The stent **10** is temporarily provided with cylindrical support ends **20**, which are not radially expandable to support the stent **10** during the polishing process. An interior polishing fixture **100** is provided which has cylindrical chambers **135** therein adapted to receive a stent **10** therein. Fluid abrasive media M then flows into bores **108** in the fixture **100** leading to the cylindrical chambers **135** and adjacent the inner diameter surfaces of the stent **10**. Surfaces of the stent **10** forming the outer diameter are polished by placing the stent **10** within an exterior polishing fixture **200** which has a cylindrical recess **220** therein. The cylindrical recess **220** has a diameter greater than a diameter of outer surfaces of the stent **10** and includes a cylindrical shaft **270** passing axially through the cylindrical recess **220** upon which the stent **10** is located. Slanted bores **208** pass through walls of the exterior polishing fixture **200** and into the cylindrical recess **220**, directing the abrasive media M adjacent exterior surfaces of the stent 10 and causing polishing of the exterior surfaces of the stent **10**. The direction of abrasive media M flow can be reversed to make streamlining of segments of the stent **10** occur in a symmetrical fashion. After polishing of the stent **10** is completed, the cylindrical support ends **20** are removed and the stent **10** is ready for implantation and radial expansion within a body lumen L. When polished and streamlined, the radially expandable surgical stent **10** more effectively supports a body lumen L without excessive thrombus, restenosis and other medical complications.

5 Claims, 7 Drawing Sheets



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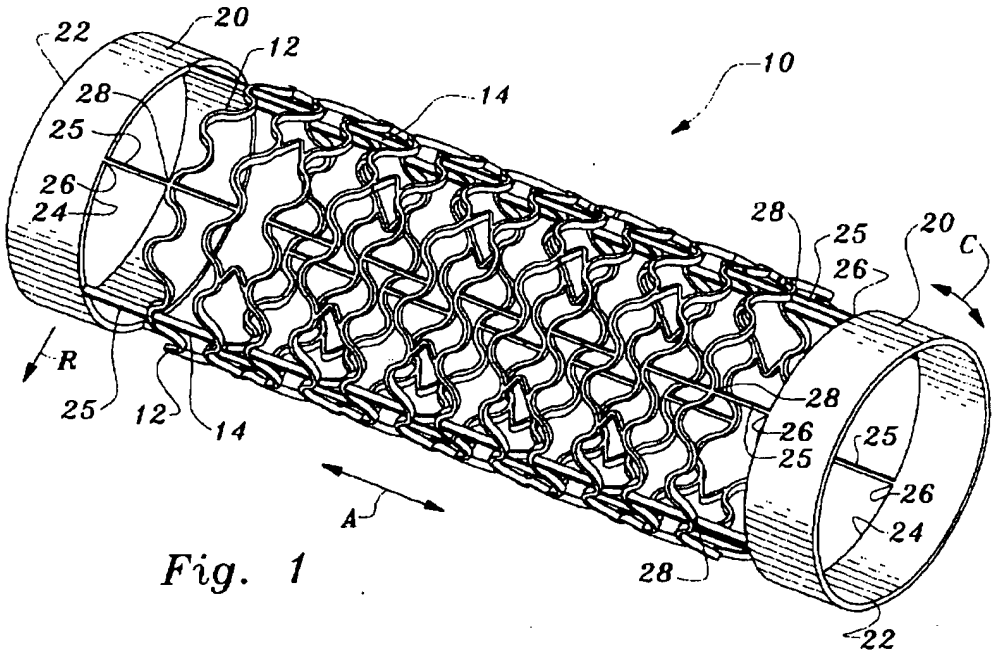
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Fig. 1

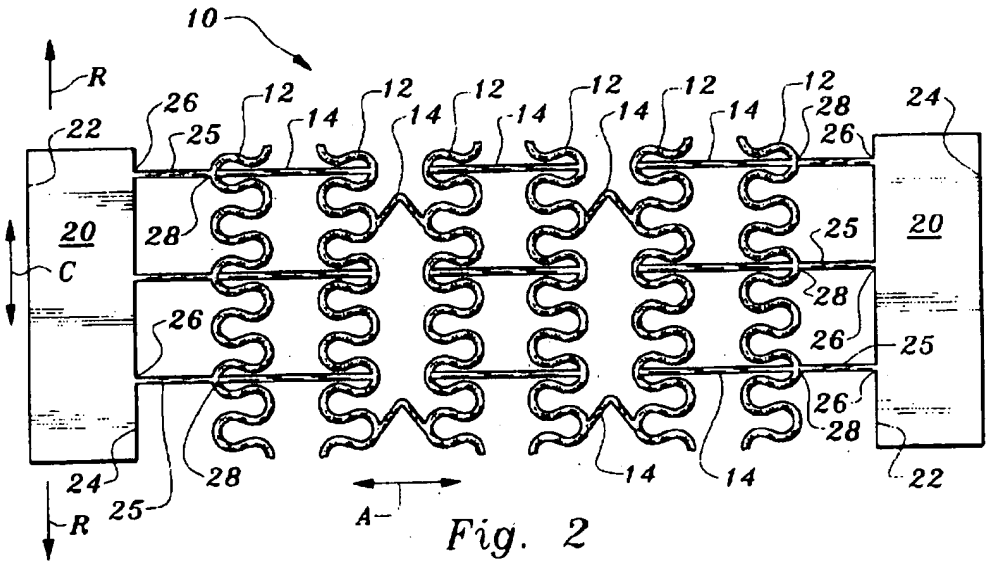
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Fig. 2

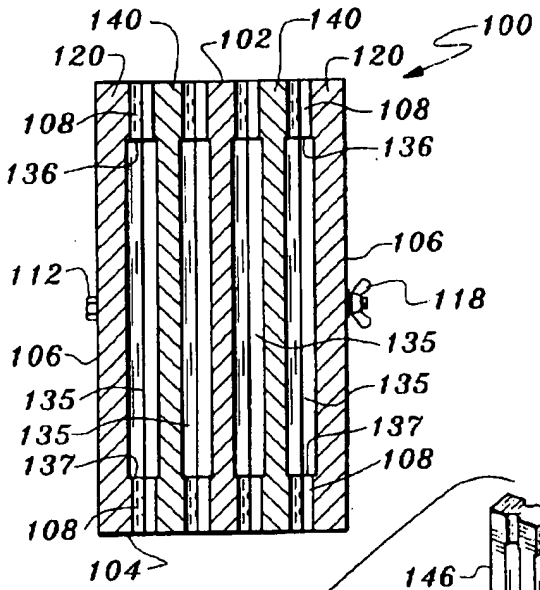

Fig. 4

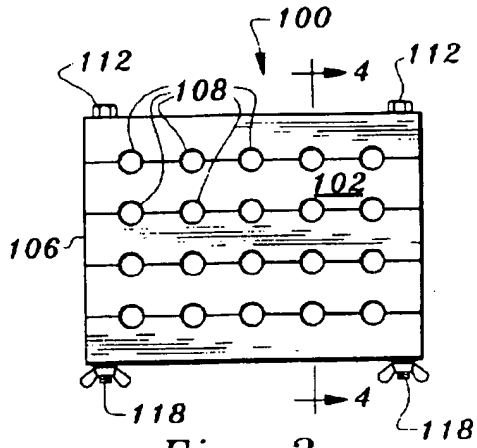

Fig. 3

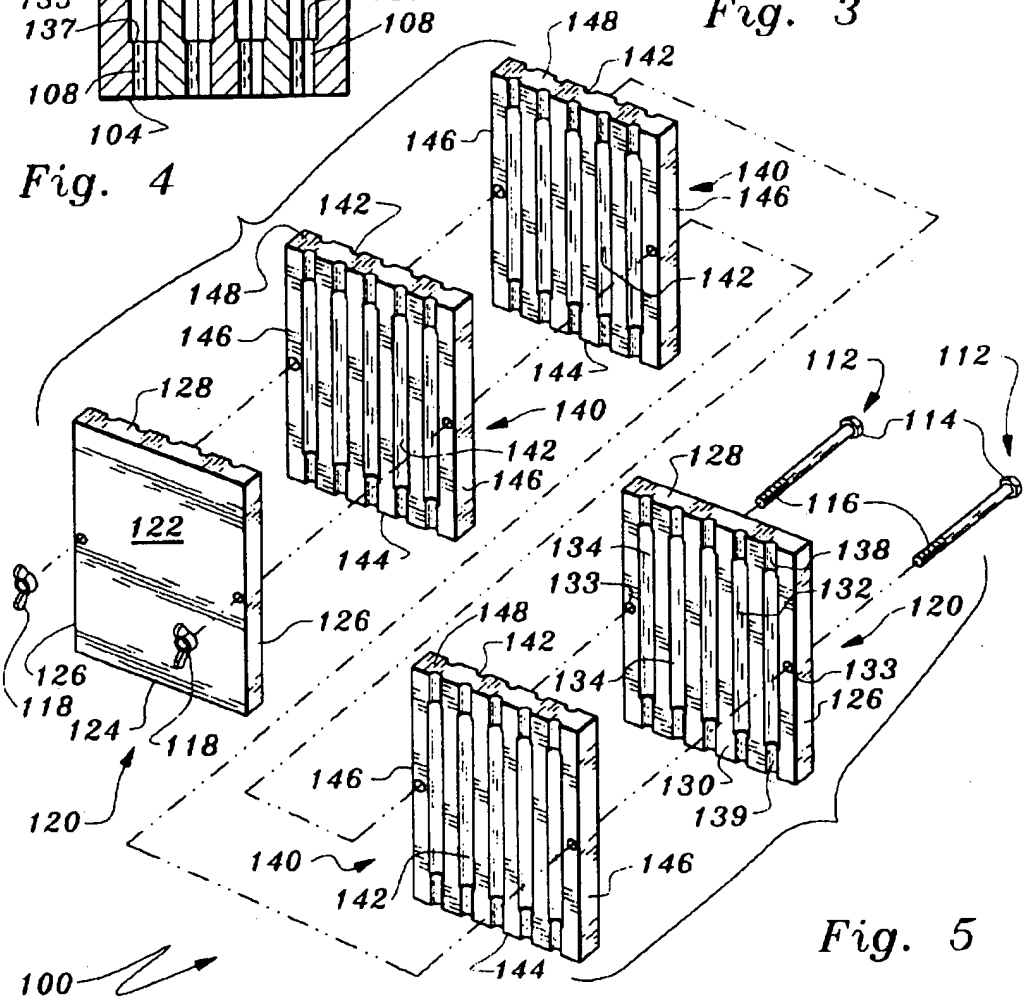

Fig. 5

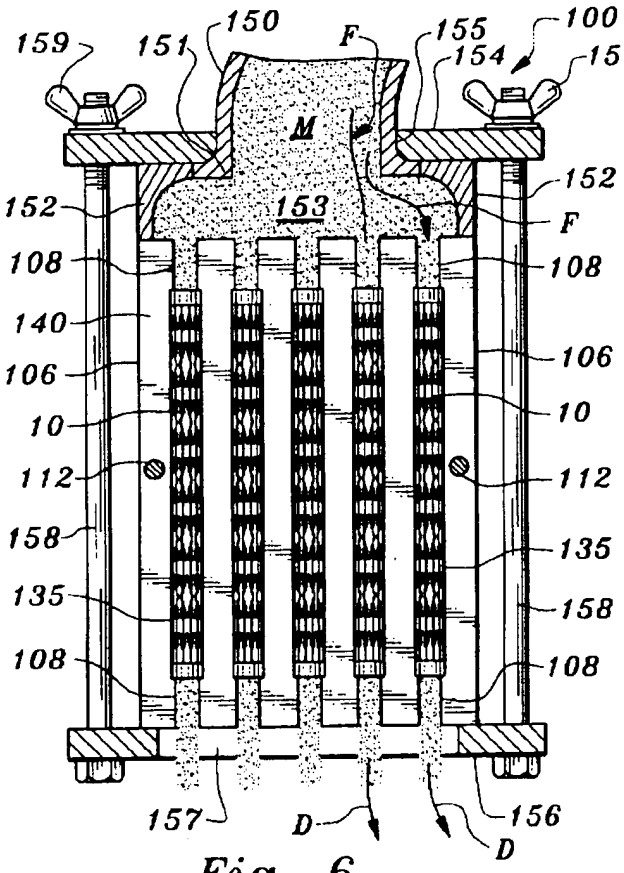

Fig. 6

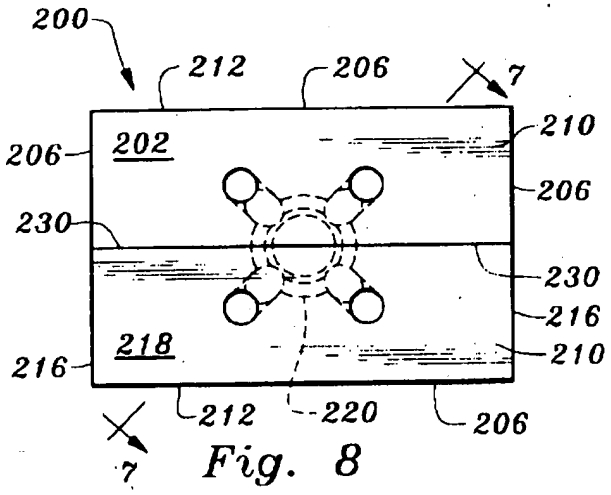

Fig. 8

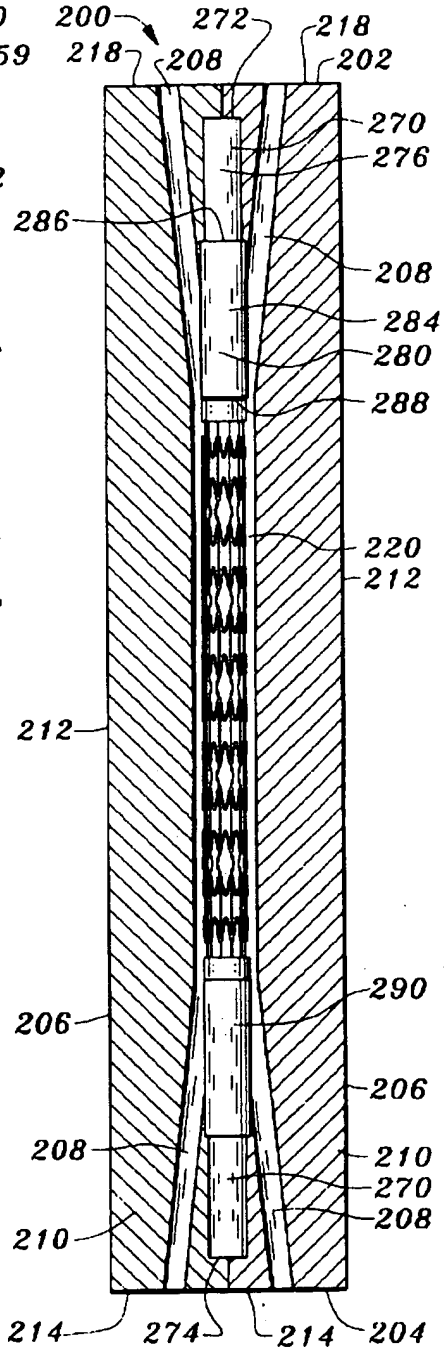

Fig. 7

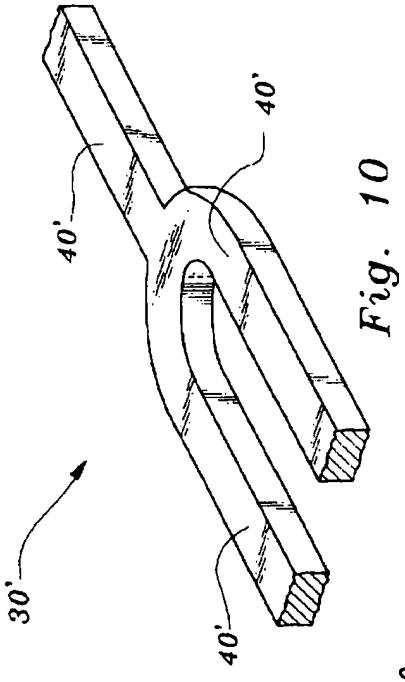

Fig. 10

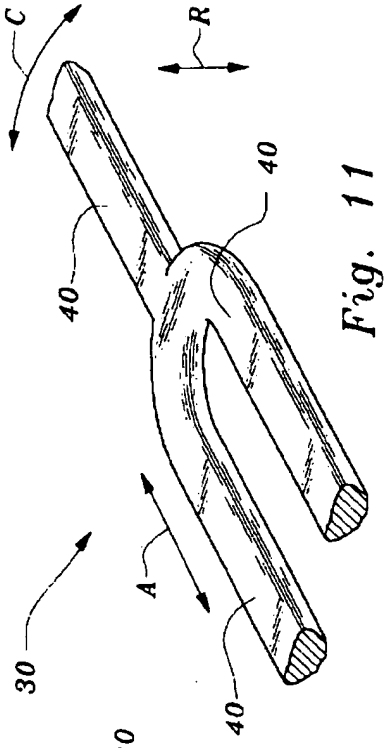

Fig. 11

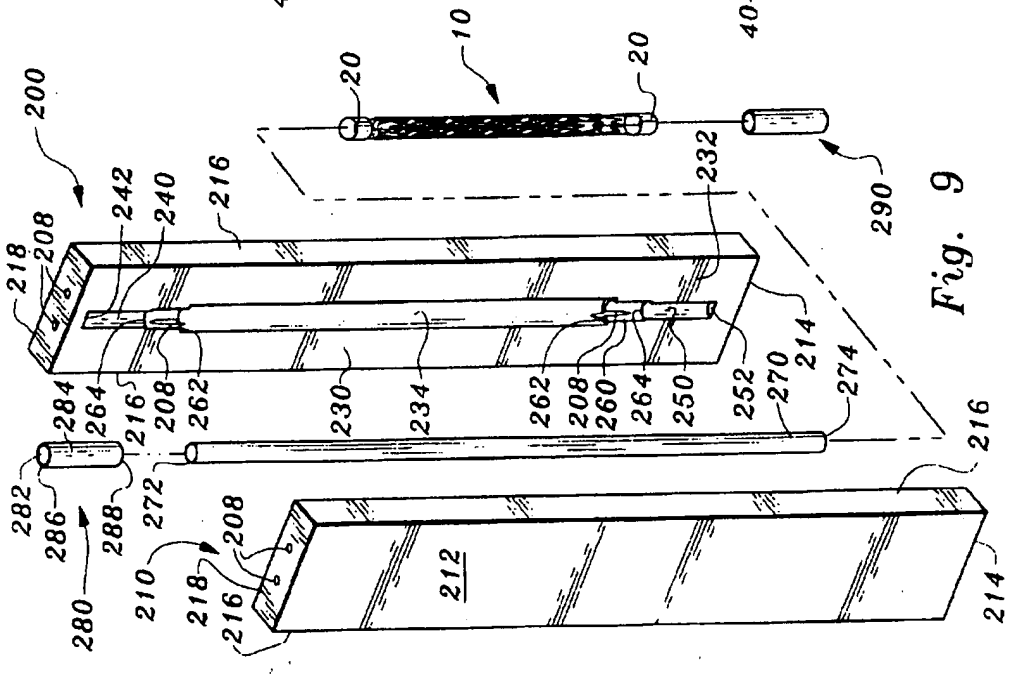

Fig. 9

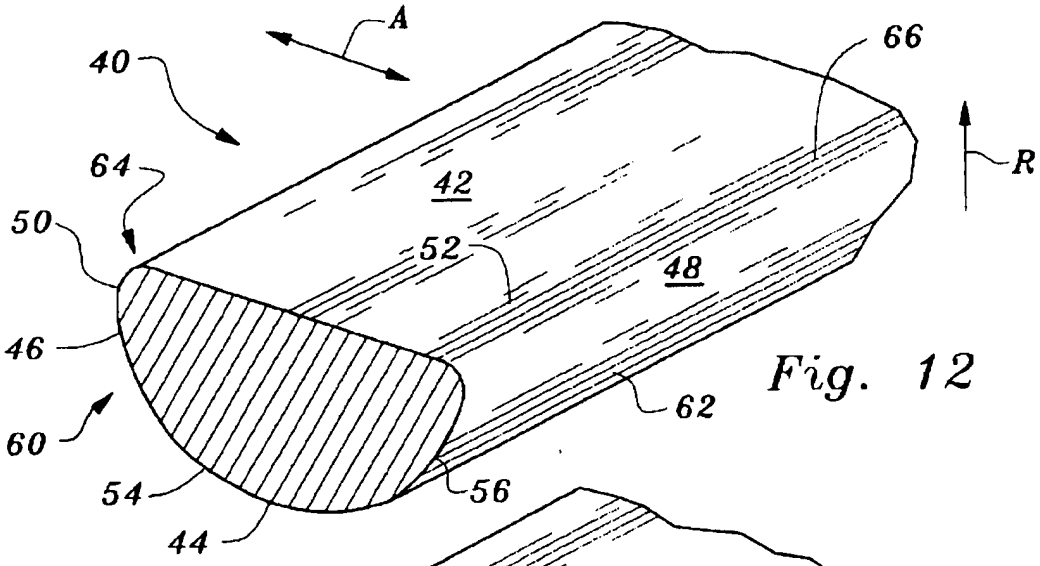

Fig. 12

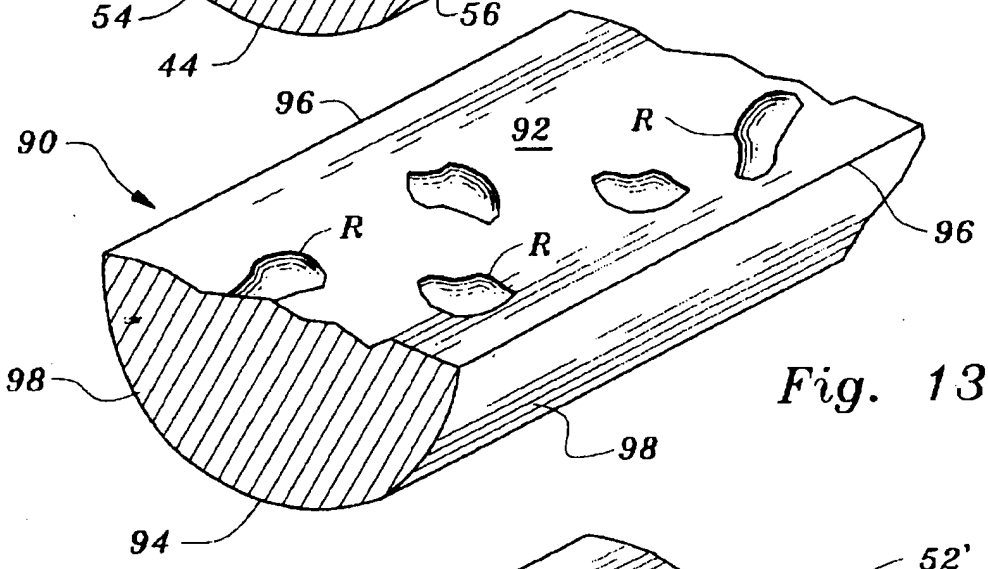

Fig. 13

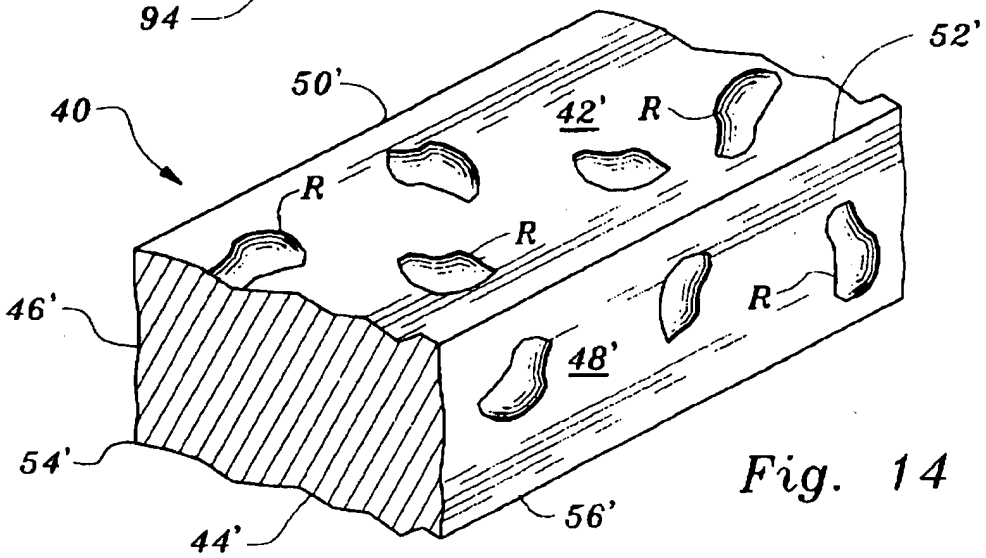

Fig. 14

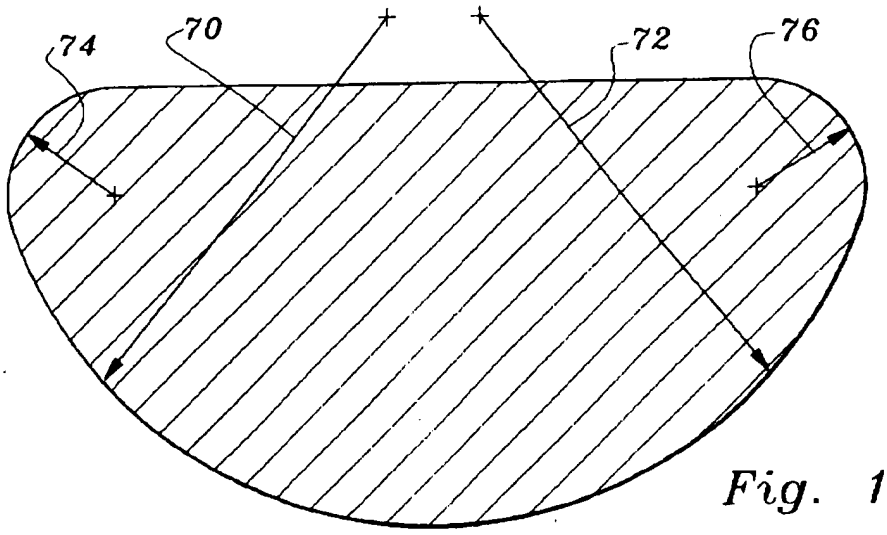

Fig. 15

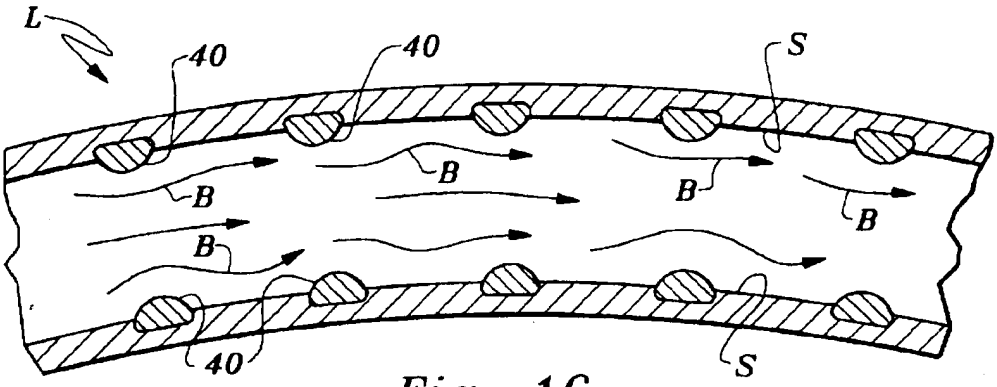

Fig. 16

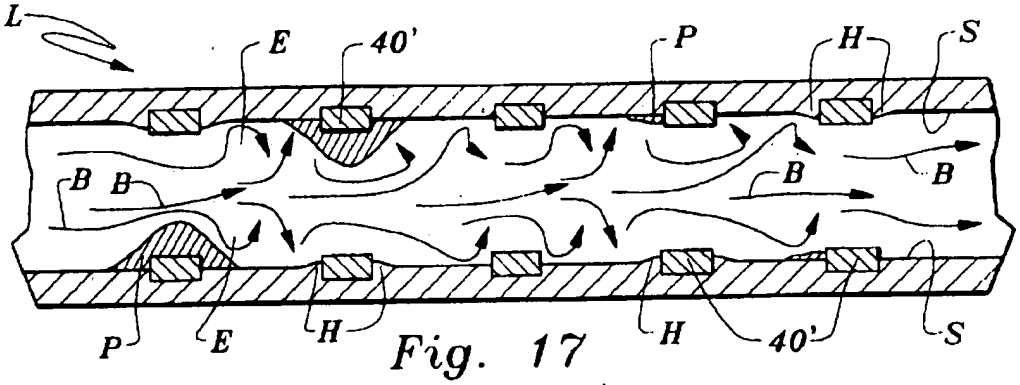

Fig. 17
(PRIOR ART)

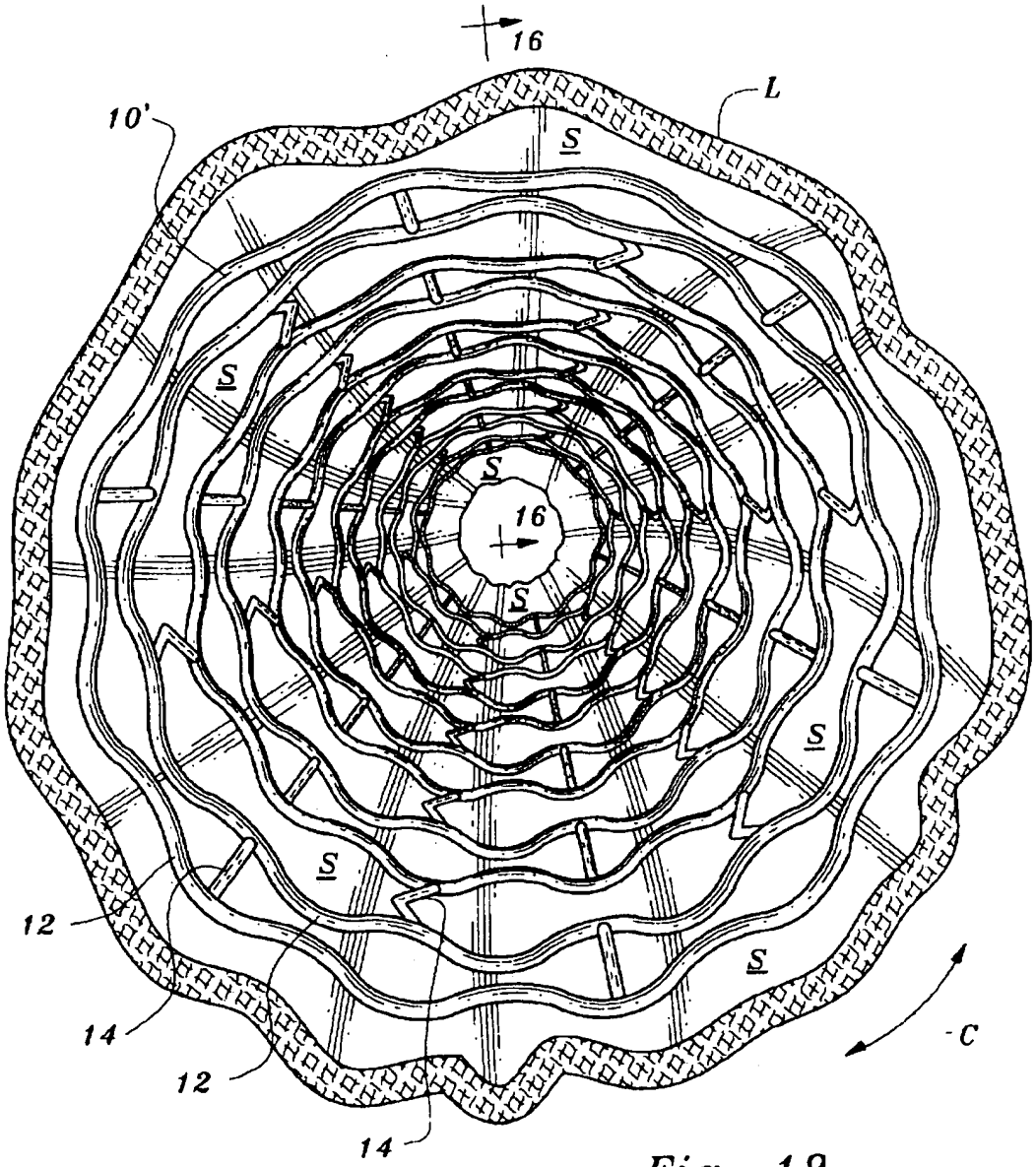

Fig. 18

METHOD FOR POLISHING SURGICAL STENTS

FIELD OF THE INVENTION

The following invention relates to the polishing of radially expandable surgical stents which can be surgically implanted into a body lumen, such as an artery, and be radially expanded to support the lumen. More specifically, this invention relates to fixtures used for supporting a radially expandable surgical stent while an abrasive media is flowed over surfaces of the stent to polish the stent and provide an inner surface of the stent with a streamlined contour, and methods for using such fixtures while polishing surgical stents.

BACKGROUND OF THE INVENTION

Surgical stents have long been known which can be surgically implanted into a body lumen, such as an artery, to reinforce, support, repair or otherwise enhance the performance of the lumen. For instance, in cardiovascular surgery it is often desirable to place a stent in the coronary artery at a location where the artery is damaged or is susceptible to collapse. The stent, once in place, reinforces that portion of the artery allowing normal blood flow to occur through the artery. One form of stent which is particularly desirable for implantation in arteries and other body lumens is a tubular stent which is formed as a complete tubular cylinder and can be radially expanded from a first smaller diameter to a second larger diameter. Such radially expandable stents can be inserted into the artery by being located on a catheter and fed internally through the arterial pathways of the patient until the unexpanded stent is located where desired. The catheter is fitted with a balloon or other expansion mechanism which exerts a radial pressure outward on the stent, causing the stent to expand radially to a larger diameter. Such expandable stents exhibit sufficient rigidity after being expanded that they will remain expanded after the catheter has been removed.

Radially expandable stents come in a variety of different configurations to provide optimal performance in various different particular circumstances. For instance, the patents to Lau (U.S. Pat. Nos. 5,514,154, 5,421,955, and 5,242,399), Baracci (U.S. Pat. No. 5,531,741), Gaterud (U.S. Pat. No. 5,522,882), Gianturco (U.S. Pat. Nos. 5,507,771 and 5,314,444), Termin (U.S. Pat. No. 5,496,277), Lane (U.S. Pat. No. 5,494,029), Maeda (U.S. Pat. No. 5,507,767), Marin (U.S. Pat. No. 5,443,477), Khosravi (U.S. Pat. No. 5,441,515), Jessen (U.S. Pat. No. 5,425,739), Hickle (U.S. Pat. No. 5,139,480), Schatz (U.S. Pat. No. 5,195,984), Fordenbacher (U.S. Pat. No. 5,549,662) and Wiktor (U.S. Pat. No. 5,133,732), each include some form of radially expandable stent for implantation into a body lumen.

Some problems which have been exhibited by prior art stents include that the inner and outer surfaces of the stents are not sufficiently streamlined or finely enough polished to prevent certain medical complications. For instance, thrombus, a phenomenon where a fibrous clot forms within cracks and other irregularities in the surface finish of an implanted object (such as a stent), is enhanced when the surfaces of the stent are not finely polished. Additionally, when the inner surface of the stent is substantially planar and has abrupt edges along borders thereof, turbulence is introduced into the blood. When a stent having such an abrupt edge is implanted into an artery, plaque and other deposits are provided with a site for collection and potential narrowing of the arteries and restriction of blood flow. This plaque buildup adjacent an implanted object (such as a stent) is referred to as "restenosis."

While many prior art stents do exhibit somewhat polished surfaces, they are typically not sufficiently finely polished, especially on tubular stents having smaller diameters, to prevent restenosis and thrombus adjacent the stent after the stent is implanted into the artery. Such prior art stents also lack a streamlined contour to minimize disruption of bodily fluid flow through the lumen and to further discourage restenosis surrounding the stent.

A primary reason why prior art stents fail to exhibit sufficiently finely polished surfaces to avoid the drawbacks discussed above is the lack of a polishing process which can effectively provide the finely polished surface desired, especially on stents having smaller inner diameters. Stents are typically polished in one of two processes, either chemical etching or electropolishing. With chemical etching, chemicals are used which react chemically with the material forming the stent, causing the material forming the stent to be driven into solution. Chemicals are selected which have a strength sufficient to cause rough areas of the stent to be dissolved, but not so strong that smooth areas of the stent are detrimentally altered. Chemical etching, while somewhat effective in removing gross irregularities from the surfaces of the stent, fail to adequately provide the desired finely polished surface.

Electropolishing typically involves providing an electrolytic solution, placing the stent within the electrolytic solution, placing a cathode within the solution and not contacting the stent and coupling an anode to the stent. When an electric voltage is provided between the anode and the cathode, the stent is caused to lose portions of its outer surface when the elements forming the stent are driven into solution and carried to the cathode for deposition upon the cathode. In essence, such electrolytic polishing is the reverse of commonly used electrical plating processes with material from the surface of the stent being removed rather than added to the stent. The rougher surfaces of the stent are more readily driven into solution and hence removed from the surfaces of the stent, smoothing the surfaces of the stent somewhat.

Because the surfaces of the stent forming the inner diameter of the stent benefit from a high degree of polishing, one known technique is to form the cathode as a thin wire passing along a central axis of the stent entirely through the stent from one end to the other, but without physically contacting the stent. When a voltage is provided between the cathode wire passing along the central axis of the stent and the stent itself, the inner surfaces of the stent are provided with the greatest electric field density and hence are the surfaces which are most polished during this process. While typically more effective than chemical etching, electrolytic polishing also fails to provide a sufficiently finely polished stent to significantly discourage thrombus and restenosis adjacent surfaces of the stent.

Accordingly, a need exists for a method and apparatus for polishing surfaces of a radially expandable surgical stent, and particularly the surfaces forming the inner diameter of the stent, with a sufficient degree of polish to reduce or eliminate the occurrence of thrombus and restenosis when surgical stents are implanted within a body lumen.

SUMMARY OF THE INVENTION

The radially expandable surgical stent which is polished and streamlined by the method and apparatus of this inven-

tion exhibits an overall tubular cylindrical hollow seamless contour which can feature any of a variety of different arrangements for individual elements and segments forming the stent. The various different segments of the stent have a generally elongate, substantially constant cross-sectional contour which can either be oriented to extend axially, circumferentially, or some combination thereof, with each segment located between an inner diameter of the stent and an outer diameter of the stent. Each segment includes an outer surface coextensive with the outer diameter of the stent and an inner surface coextensive with the inner diameter of the stent. Each segment also includes lateral surfaces extending between the inner surface and the outer surface which can either be a leading surface on an upstream side of the segment, a trailing surface on a downstream side of the segment, or a lateral surface generally aligned axially with the stent.

The inner surface of each segment of the stent is extensively streamlined by the polishing method and apparatus of this invention to minimize disruption of bodily fluid flow through the body lumen. Specifically, the inner surface includes an inner leading edge and an inner trailing edge bordering the inner surface. Each inner edge is defined by an inner curve having a relatively large radius of curvature when compared to the radii of curvature exhibited by outer edges adjacent the outer surface of each stent segment. Because the inner edges have a large radius of curvature, they do not present any abrupt transition in flow for bodily fluids passing over the inner surface of the stent segment, particularly when the stent segment is aligned circumferentially with bodily fluid flow passing adjacent the inner surface from a leading inner edge to a trailing inner edge.

The surfaces of each stent segment are honed and polished to have a surface finish which is free from abrupt transitions and irregularities, such as prominences extending more than five micro inches above adjacent portions of the surrounding surface. Smooth flow of blood or other bodily fluids over the surfaces of the stent can thus be preserved and a risk of medical complications such as restenosis and thrombus can be minimized.

The polishing apparatus of this invention includes a fixture which rigidly supports at least one radially expandable surgical stent within a cylindrical chamber in the fixture. A bore passes through the fixture and leads both into the cylindrical chamber and out of the cylindrical chamber. A source of fluid abrasive media is placed adjacent the fixture in an orientation which allows the fluid abrasive media to pass through the bores and into the cylindrical chamber. The cylindrical chamber has a diameter similar to the outer diameter of the stent so that the fluid abrasive media is forced to pass only through the interior of the stent and adjacent the surfaces forming the inner diameter of the stent. As the fluid abrasive media passes through the cylindrical chamber and adjacent the surfaces forming the inner diameter of the stent, the surfaces forming the inner diameter of the stent are polished to a level of smoothness determined by the particle size of the abrasive media, the amount of time which the abrasive media flows past the surfaces of the stent and other factors known in the honing arts.

When it is desired that the outer diameter of the stent be polished, a stent exterior polishing fixture is provided having a cylindrical recess located therein with slanted bores leading from a top and bottom of the fixture to the cylindrical recess. The cylindrical recess has a diameter greater than the diameter of the outer diameter of the stent. A shaft is located within the cylindrical recess with a central axis of the shaft aligned with a central axis of the cylindrical recess. The shaft has a diameter similar to the inner diameter of the stent. The stent is placed on the shaft and within the cylindrical recess so that abrasive media flowing through the slanted bores and into the cylindrical recess are precluded from flowing adjacent the surfaces forming the inner diameter of the stent, but rather flow adjacent surfaces forming the outer diameter of the stent for polishing of the outer diameter of the stent.

In utilizing the various fixtures for supporting the stent during this polishing process, the stent is preferably initially provided with non-radially expanding cylindrical support ends adjacent each end of the stent. These cylindrical support ends are located along with the stent within the cylindrical chamber or cylindrical recess of one of the fixtures and provide additional support for the stent during the polishing process. The support ends prevent collapse of the stent and excessive polishing of ends of the stent during the polishing process.

The polishing process can be additionally facilitated by ultrasonically vibrating the abrasive media and elevating the pressure of the abrasive media as it flows through the fixture and adjacent surfaces of the stent. If it is desired that the stent be provided with a streamlined contour which is not biased in any one direction, the stent can be removed and reoriented within the fixture for polishing in a reverse direction or the fixture can be disconnected from the source of abrasive media, rotated 180° and recoupled to the source of abrasive media for polishing in a reverse direction. Once the polishing process is completed, the cylindrical support ends are removed from the stent. The stent is then ready for implantation within a body lumen with such finely polished surfaces that restenosis and thrombus are minimized.

OBJECTS OF THE INVENTION

Accordingly, a primary object of the present invention is to provide a method for polishing surfaces of a radially expandable surgical stent which includes flowing a fluid abrasive media adjacent surfaces of the stent to be polished until the stent exhibits a desired finish.

Another object of the present invention is to provide a method for streamlining surfaces of a radially expandable surgical stent by flowing fluid abrasive media adjacent surfaces of the stent to be streamlined.

Another object of the present invention is to provide a method for polishing a radially expandable surgical stent which can polish multiple stents simultaneously.

Another object of the present invention is to provide a fixture for a radially expandable surgical stent polishing process which holds and supports the stent while fluid abrasive media is flowed adjacent surfaces of the stent and which can be easily loaded and unloaded with stents to be polished.

Another object of the present invention is to provide a fixture for a stent polishing process which restricts fluid abrasive media flow to the surfaces forming the inner diameter of the stent.

Another object of the present invention is to provide a fixture for a stent polishing process which restricts fluid abrasive media flow to the surfaces forming the outer diameter of the stent.

Another object of the present invention is to provide a stent polishing fixture which can be readily attached to honing equipment which uses elevated pressure fluid abrasive media and ultrasonic vibration of the fluid abrasive media and directs the fluid abrasive media through the fixture.

Another object of the present invention is to provide a surgical stent which minimizes medical complications such as restenosis and thrombus adjacent the stent.

Another object of the present invention is to provide a radially expandable surgical stent which has a finish smoothness which minimizes medical complications such as restenosis and thrombus adjacent the stent when the stent is implanted within an artery or other body lumen.

Another object of the present invention is to provide a surgical stent which can support a body lumen while minimizing disruption of flow of bodily fluids through the lumen.

Another object of the present invention is to provide a surgical stent which is reversible and can be implanted in two distinct orientations rotated 180° from each other without altering performance of the surgical stent.

Another object of the present invention is to provide a surgical stent which features an inner surface which has edges with greater radii of curvature than radii of curvature of outer edges bordering an outer surface of segments of the stent, such that disruption to blood flow within a body lumen in which the stent is implanted is minimized and the outer surface of the stent is securely held adjacent a wall of the lumen.

Other further objects of the present invention will become apparent from a careful reading of the included description and claims and from a review of the drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a radially expandable surgical stent with cylindrical support ends located adjacent each end of the stent, such that the stent is ready to be placed within a fixture for polishing of surfaces of the stent. The stent is shown with circumferential elements radially expanded to make surfaces of the stent more readily discernible. However, the circumferential elements of the stent would in fact be not radially expanded when attached to the cylindrical support ends.

FIG. **2** is a cylindrical projection of a portion of that which is shown in FIG. **1** with the circumferential elements shown not radially expanded as the circumferential elements would appear when attached to the cylindrical support ends and during the polishing process of this invention.

FIG. **3** is a top plan view of a stent interior surface polishing fixture for use according to the polishing method of this invention.

FIG. **4** is a full sectional view of that which is shown in FIG. **3** taken along lines **4—4** of FIG. **3**.

FIG. **5** is a perspective exploded parts view of that which is shown in FIG. **3** revealing how separate plates of the fixture are coupled together to form the fixture of FIG. **3**.

FIG. **6** is a sectional view of the fixture of FIG. **3** with other portions of the honing equipment and fluid abrasive media supply attached to the fixture and revealing how fluid abrasive media is caused to flow through the fixture and adjacent surfaces of the stent forming the inner diameter of the stent.

FIG. **7** is a full sectional view taken along lines **7—7** of FIG. **8** and revealing details of a polishing fixture for polishing exterior surfaces of a stent.

FIG. **8** is a top plan view of the stent exterior surface polishing fixture with interior details thereof shown with broken lines to show locations of voids within the fixture.

FIG. **9** is a perspective exploded parts view of that which is shown in FIGS. **7** and **8** revealing how the stent is oriented within the stent exterior surface polishing fixture for polishing of exterior surfaces forming the outer diameter of the stent.

FIG. **10** is a perspective view of a portion of an alternative stent before any polishing of surfaces of the stent has occurred.

FIG. **11** is a perspective view of that which is shown in FIG. **10** after polishing of surfaces of the stent has been completed according to this invention.

FIG. **12** is a perspective view of a portion of that which is shown in either the stent of FIG. **11** or the stent of FIGS. **1** and **2** revealing in greater detail the exact streamlined contour of the segments of the stent after the polishing method of this invention has been completed.

FIG. **13** is a perspective view of a segment of a stent when only the portions of the stent forming the inner diameter of the stent have been polished and with surfaces forming the outer diameter of the stent left unpolished.

FIG. **14** is a perspective view of a portion of that which is shown in FIG. **10** revealing how the surfaces of the stent exhibit roughness before the polishing method of this invention is performed.

FIG. **15** is a full sectional view of that which is shown in FIG. **12** revealing further details of the streamlined contour of segments of the stent after completion of the polishing method according to this invention.

FIG. **16** is a full sectional view taken along lines **16—16** of FIG. **18** and showing a body lumen with a stent, polished according to this invention, located within the body lumen and radially expanded within the body lumen to support walls of the lumen.

FIG. **17** is a full sectional view of a body lumen with a non-polished or minimally polished radially expandable surgical stent located therein and revealing turbulent blood flow, restenosis and thrombus within the body lumen.

FIG. **18** is a full sectional perspective end view of the polished radially expandable surgical stent in position within a body lumen and radially expanded therein.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings, wherein like reference numerals represent like parts throughout the various different drawing figures, reference numeral **10** is directed to a radially expandable surgical stent (FIG. **1**) which has been fitted with non-radially expandable cylindrical support ends **20** at each end of the stent **10**. Surfaces of the stent **10** forming an inner diameter of the stent **10** are polished by placing the stent **10** within a stent interior polishing fixture **100** (FIGS. **3–6**) and flowing fluid abrasive media M through the fixture **100** with the stents **10** therein. A stent exterior polishing fixture **200** (FIGS. **7–9**) is also provided which is configured to polish surfaces of the stent **10** forming an outer diameter of the stent **10** by flowing the abrasive media M adjacent the exterior surfaces of the stent **10**. The abrasive media M not only polishes surfaces of the stent **10** but also alters a cross-sectional contour of stent segments **40** (FIGS. **10–15**) such that an inner surface **44** is streamlined to minimize disruption of bodily fluid flow passing over the inner surface **44** when the stent **10** is implanted within a body lumen L (FIGS. **16** and **18**) after removal of the cylindrical support ends **20**.

The fixtures **100**, **200** and other details of the polishing method of this invention can be altered to polish surfaces of the stent **10** in various different manners and also to alter a

contour of surfaces of the stent **10**, such as to streamline surfaces of the stent **10**, to cause surface details of the stent **10** to match any of a variety of different desired contours and with a variety of different finish smoothnesses. However, a preferred contour for the stent **10** and stent segments **40** (FIG. **11**) of an alternative stent **30**, having slightly differently configured stent segments **40** than the circumferential elements **12** and axial elements **14** of the stent **10** (FIGS. **1** and **2**), is described in detail By altering the polishing methods discussed below, stents having different contour characteristics could similarly be generated.

In essence, and with particular reference to FIGS. **11** and **12**, the cross-sectional contour of each stent segment **40** is described, whether the stent segment **40** is taken from the stent **10** or from the alternative stent **30**. Each stent segment **40** is an elongate construct of substantially constant cross-sectional generally rectangular form, having an outer surface **42** opposite an inner surface **44**. Two lateral side surfaces including a leading surface **46** and a trailing surface **48** extend between the inner surface **44** and the outer surface **42**. The inner surface **44** is provided with an inner leading edge **54** and an inner trailing edge **56** which are defined by an inner leading curve **60** and an inner trailing curve **62**, respectively, with sufficiently high radii of curvature **70**, **72** (FIG. **15**) that the inner surface **44** is highly streamlined between the inner leading edge **54** and the inner trailing edge **56**.

The outer surface **42** extends between two side edges including an outer leading edge **50** and an outer trailing edge **52**. The outer leading edge **50** is defined by an outer leading curve **64** and the outer trailing edge **52** is defined by an outer trailing curve **66**. The outer leading curve **64** and outer trailing curve **66** have radii of curvature **74**, **76** (FIG. **15**) which are less than the radii of curvature **70**, **72** of the inner leading curve **60** and the inner trailing curve **62** (FIG. **5**). The stent segment **40** thus has a contour which presents a highly streamlined gradually curving surface for passage of bodily fluid B (FIG. **16**) there over and the outer surface **42** presents a more abrupt contour for secure positioning adjacent an inner surface S of the body lumen L (FIGS. **16** and **18**).

Before polishing, the stent segments **40'** (FIG. **14**) of the unpolished stent **10** or alternative stent **30'** have planar parallel inner and outer surfaces **44'**, **42'** and planar parallel leading and trailing surfaces **46'**, **48'** perpendicular to the surfaces **44'**, **42'**. The stent segments exhibit abrupt edges **50'**, **52'**, **54'**, **56'** between adjacent surfaces **42'**, **44'**, **46'**, **48'**. Roughness areas R are located on the surfaces **42'**, **44'**, **46'**, **48'**. After polishing, the stent segments **40** have greater surface smoothness and a cross-sectional contour which is more streamlined than the stent segment **40'**. Specific details of the geometry and other features of the polished and streamlined stent **10** and its alternatives are incorporated by reference from U.S. patent application Ser. No. 08/839,434, filed on Apr. 10, 1997, entitled "SURGICAL STENT HAVING A STREAMLINED CONTOUR."

In use and operation, when a stent **10** featuring stent segments **40** of this invention is implanted into a lumen L (FIGS. **16** and **18**) with the stent segments **40** embedding slightly into the inner surface S of the lumen L and supporting the lumen L, blood/fluid flow B is only slightly disrupted and restenosis and plaque buildup is minimized. When prior art stents are implanted (FIG. **17**) stent segments **40** having more abrupt contours cause disruption in the blood/fluid flow B producing eddies E which further disrupt blood/fluid flow B and encourage the formation of plaque P, leading to restenosis, along the inner surface S at various locations along the inner surface S. Thrombus H is also stimulated by irregularities in surface finish exhibited by stent segments **40'** of prior art stents.

Because the leading curves **60**, **64** generally match the contour of the trailing curves **62**, **66** of each stent segment **40**, the stent **10** featuring the stent segment **40** can be reversed 180° with similar function in either orientation. Alternatively, should maximum streamlining of the stent segment **40** be desired, the inner surface **44** can be provided with a more airfoil-like asymmetrical contour which does not provide the leading surface **46** and trailing surface **48** as mirror images of each other, but rather provides the leading surface **46** with a smaller radius of curvature and the trailing surface **48** with a larger radius of curvature or a tapering gradual slope, somewhat analogous to that of a tear drop in cross-section. Such an asymmetrical surgical stent would necessarily only benefit from its form when implanted in a particular direction with regard to blood/fluid flow B through the lumen L.

Having thus described in detail the preferred contour and finished smoothness for the stent **10**, it should be apparent that should different finished smoothnesses be desired, for various different purposes, various different curvatures and measurements of the contour of the stent **10** could be similarly provided. This is particularly true when utilizing the polishing method disclosed below. To accomplish polishing and streamlining of the stent **10** to exhibit the contour discussed above, or any other desired contour, the following method is utilized with the apparatus discussed in detail below.

Before polishing the stent **10** according to the method of this invention, the stent **10** is preferably slightly modified to provide additional support to the stent **10** during the polishing process. Specifically, cylindrical support ends **20** are attached to each end of the stent **10**. Each cylindrical support end **20** is a cylindrical hollow substantially rigid construct preferably formed from the same material with which the circumferential elements **12** and axial elements **14** of the stent **10** are formed. Each cylindrical support end **20** includes an outer edge **22** on an end of the cylindrical support end **20** most distant from the stent **10** and an inner edge **24** opposite the outer edge **22** and adjacent the stent **10**.

A plurality of ties **25** extend from the inner edge **24** to the portions of the stent **10** adjacent to each cylindrical support end **20**. The ties **25** are preferably linear elongate segments of the stent **10** which are oriented in an axial direction (along arrow A of FIGS. **1** and **2**) and are colinear with axial elements **14** adjacent to the cylindrical support ends **20**. Preferably six ties **25** extend between the inner edge **24** and the portions of the stent **10** adjacent the cylindrical support ends **20**. Each tie **25** includes an outer end **26** adjacent the inner edge **24** and an inner end **28** opposite the outer end **26** and attached to the end of the stent **10** adjacent the cylindrical support end **20**.

The cylindrical support ends **20** can either be attached to the ends of the stent **10** before the polishing process or the cylindrical support ends **20** can be formed along with other portions of the stent **10** originally so that the cylindrical support ends **20** are attached to the stent **10** at all times up until the polishing process is completed. After the polishing process is completed, the cylindrical support ends **20** are removed from ends of the stent **10** along with the ties **25**, providing the stent **10'** (FIG. **18**) in the desired configuration for implantation within a body lumen L.

The cylindrical support ends **20** are not radially expandable. Thus, the cylindrical support ends **20** help support the stent **10** during the polishing process and prevent the stent **10**

from being prematurely radially expanded. Additionally, the cylindrical support ends **20** provide a leading edge for the stent **10** during the polishing process and reduce a risk that abrasive media M flowing along surfaces of the stent **10** will cause circumferential elements **12** at ends of the stent **10** to be collapsed or to otherwise collapse the stent **10** axially (along arrow A of FIGS. **1** and **2**) due to the added rigidity of the stent **10** when the cylindrical support ends **20** are attached thereto. Preferably, inner and outer diameters of the cylindrical support ends **20** match inner and outer diameters of the stent **10**.

With reference to FIG. **2**, further details of the stent **10** with the cylindrical support ends **20** attached thereto are provided. Reference arrow C indicates a circumferential direction and reference arrows R represent the radially direction in which the stent **10** is radially expanded after removal of the cylindrical support ends **20** from the stent **10**. FIG. **2** shows the circumferential elements **12** in an undulating fashion having not yet been radially expanded, as is the case while the cylindrical support ends **20** are attached thereto. In contrast, FIG. **1** shows the circumferential elements **12** radially expanded to illustrate the difference in the configuration of the stent **10** after radial expansion. The cylindrical support ends **20** would not be attached to other portions of the stent **10** when the stent **10** has been radially expanded, along arrow R. Hence, FIG. **1** is a composite view which would not actually exist, but depicts the configuration of the cylindrical support ends **20** in perspective and a perspective view of the radially expandable surgical stent **10** after it has been radially expanded.

While various different systems could be utilized to effectively flow abrasive media past surfaces of the stent **10** for polishing, a preferred system for effectively flowing the fluid abrasive media M past surfaces of the stent **10**, and particularly for polishing surfaces of the stent **10** forming an inner diameter of the stent **10**, are provided by the stent interior polishing fixture **100** (FIGS. **3–6**). The stent interior polishing fixture **100** is a rigid construct configured to provide a means to hold a series of stents **10** motionless and provide conduits for fluid abrasive media M to flow adjacent surfaces of the stent **10** forming an inner diameter of the stent **10**. The interior polishing fixture **100** includes a top **102** parallel to and spaced from a bottom **104**. Four parallel sides **106** are oriented perpendicular to the top **102** and bottom **104**. Hence, the top **102**, bottom **104** and sides **106** form an orthorhombic rigid mass of solid material.

A series of bores **108** pass from the top **102** through to the bottom **104** of the fixture **100**. Preferably, each bore **108** is cylindrical in form and passes along a line perpendicular to the top **102** and the bottom **104**. Preferably, the bores **108** have a diameter which is similar to the inner diameter of the stent **10**. The fixture **100** is preferably not formed from a single unitary mass of material but rather from a series of rigid plates including two end plates **120** and a plurality of mid-plates **140** sandwiched between the two end plates **120**.

Each of the plates **120**, **140** is securely held together with closure bolts **112** passing through the interior polishing fixture **100** in an orientation parallel to the top **102** and bottom **104** of the fixture **100** and perpendicular to adjacent surfaces of the end plates **120**. Preferably, two closure bolts **112** are provided passing through the fixture **100** at locations which prevent the closure bolts **112** from intersecting with the bores **108**. Each closure bolt **112** includes a head **114** on an end of each bolt **112** opposite a threaded tip **116**. Wing nuts **118** are provided which thread onto the threaded tip **116**. The closure bolts **112** can pass through the plates **120**, **140** forming the fixture **100** with the head **114** of each closure bolt **112** adjacent one of the end plates **120** and the wing nuts **118** threaded onto the closure bolts **112** adjacent the opposite end plate **120**. By tightening the wing nuts **118** against the end plate **120**, the plates **120**, **140** are securely sandwiched together without motion.

The bores **108** are aligned to pass between an end plate **120** and a mid-plate **140** or between two adjacent mid-plates **140**. In this way, access is provided to a cylindrical chamber **135** within the bore **108** when the plates **120**, **140** of the interior polishing fixture **100** are separated away from each other. Preferably, three mid-plates **140** are provided between the two end plates **120** and five bores **108** are provided at each transition between an end plate **120** and an adjacent mid-plate **140** and between adjacent mid-plates **140**, such that a total of twenty bores **108** are provided passing from the top **102** to the bottom **104** of the interior polishing fixture **100**.

With particular reference to FIG. **5**, specific details of each end plate **120** are provided. Each end plate **120** is a unitary rigid mass of material which forms a portion of the interior polishing fixture **100**. Each end plate **120** includes an outer surface **122** which does not include any portion of a bore **108** thereon. Each end plate **120** includes a bottom **124** parallel to and spaced from a top **128** which form portions of the top **102** and bottom **104** of the interior polishing fixture **100**. Each end plate **120** also includes lateral sides **126** parallel to each other and oriented perpendicular to the bottom **124** and top **128**.

An inner surface **130** is provided on the side of the end plate **120** opposite the outer surface **122**. This inner surface **130** is similarly formed on each of the two end plates **120**. The inner surface **130** is contoured to include portions of the bores **108** therein. Each inner surface **130** includes a flat plane **132** defining portions of the inner surface **130** which do not include portions of the bores **108** therein. Two bolt holes **133** pass through the inner surface **130** and entirely through to the outer surface **122** of each end plate **120**. The bolt holes **133** have a diameter which accommodates passage of the closure bolts **112** there through. The bolt holes **133** are preferably located at a position intermediate between the bottom **124** and top **128** of the end plate **120** and between a lateral side **126** of the end plate **120** and a closest bore **108**. Alternatively, the bolt holes **133** can be located at any location on the inner surface **130** where the flat plane **132** is provided, rather than a portion of a bore **108**.

Each bore **108** includes a void defined by a cylindrical chamber **135** therein. The cylindrical chamber **135** is formed by having a cylindrical chamber wall **134** contoured into the inner surface **130** of each end plate **120**. Preferably, with five bores **108** passing between each end plate **120** and an adjacent mid-plate **140**, five cylindrical chamber walls **134** are formed in the inner surface **130**. The cylindrical chamber wall **134** is semi-cylindrical in form providing exactly one-half of the cylindrical chamber **135**. The cylindrical chamber wall **134** does not extend all the way up to the top **128** or to the bottom **124** of the end plate **120**. Rather, the cylindrical chamber wall **134** forms an interior detail of one of the bores **108** which does not extend to the top **102** and bottom **104** of the interior polishing fixture **100**.

The cylindrical chamber wall **134** preferably has a diameter similar to an outer diameter of the stent **10**. The cylindrical chamber wall **134** extends from a top chamber end **136** to a bottom chamber end **137** (FIG. **4**). Above the top chamber end **136** a top cylindrical bore wall **138** (FIG. **5**) is provided forming a portion of the bore **108** extending from the cylindrical chamber **135** up to the top **102** of the

fixture **100**. A bottom cylindrical bore wall **139** (FIG. 5) similarly extends from the bottom chamber end **137** to the bottom **104** of the interior polishing fixture **100**.

The top cylindrical bore wall **138** and bottom cylindrical bore wall **139** form exactly half of the cylindrical bore **108** leading into and out of the cylindrical chamber **135**. The top chamber end **136** and bottom chamber end **137** provide a transition between the larger diameter of the cylindrical chamber **135** and the smaller diameter of the bores **108**. With the top chamber end **136** and bottom chamber end **137** spaced apart similar to an axial length of the stent **10**, a stent **10** can be located within the cylindrical chamber **135** with the outer diameter of the stent **10** adjacent the cylindrical chamber wall **134** and with the cylindrical support ends **20** of the stent **10** adjacent the top chamber end **136** and bottom chamber end **137**. In this position, the inner diameter of the stent **10** is aligned with the bore walls **138**, **139** forming the bores **108**.

The mid-plates **140** are similar to the end plats **120** except that each mid-plate **140** includes two contoured surfaces **142** each similar in contour to the contour provided by the inner surface **130** of each end plate **120**. The mid-plates **140** include a bottom **144** parallel to and spaced from a top **148** with two parallel lateral sides **146** oriented perpendicular to the bottom **144** and top **148**.

With particular reference to FIG. **6**, other portions of the stent polishing apparatus which attach to the interior polishing fixture **100** are described in detail. A hose **150** is located adjacent the top **102** of the interior polishing fixture **100**. The hose **150** provides a source for fluid abrasive media M which can lead from a reservoir up to the top **102** of the fixture **100**. A lower end **151** of the hose **150** is located adjacent a manifold plate **152**. The manifold plate **152** is a rigid construct which is configured to seal against the top **102** of the fixture **100** with a manifold chamber **153** therein provided in fluid communication with each of the bores **108** in the interior polishing fixture **100**. The manifold chamber **153** is also open to the interior of the hose **150** so that fluid abrasive media M can flow through the hose **150**, out of the lower end **151** of the hose **150** and into the manifold chamber **153**; where it can then flow into each of the bores **108** in the interior polishing fixture **100**.

A top clamp plate **154** is located over the manifold plate **152** and secures the manifold plate **152** to the top **102** of the fixture **100**. A hose opening **155** is located in the top clamp plate **154** so that the hose **150** can still access the manifold chamber **153**. A bottom clamp plate **156** is located adjacent the bottom **104** of the fixture **100**. The bottom clamp plate **156** includes a central opening **157** which leaves the bores **108** in the bottom **104** unblocked. A series of clamp bolts **158** with wing nuts **159** pass through the top clamp plate **154** and bottom clamp plate **156** and can be threaded together, drawing the bottom clamp plate **156** and top clamp plate **154** toward each other and securing the manifold plate **152** and hose **150** adjacent the top **102** of the interior polishing fixture **100**.

In use and operation, the interior polishing fixture **100** is utilized to polish surfaces forming an inner diameter of the stent **10** in the following manner. Initially, the closure bolts **112** are removed from the fixture **100** and the end plates **120** and mid-plates **140** are each separated from each other. Each cylindrical chamber **135** is then preferably provided with a separate stent **10** and the end plates **120** and mid-plates **140** are placed adjacent each other with the closure bolts **112** in place securing the plates **120**, **140** together. The manifold plate **152** is then placed over the top **102** of the fixture **100** with the hose **150** interfacing with the manifold plate **152**. The top clamp plate **154** and bottom clamp plate **156** are then oriented over the top **102** and bottom **104**, respectively, of the fixture **100** and the wing nuts **159** are tightened to secure the manifold plate **152** and hose **150** in position adjacent the top **102** of the fixture **100**.

Fluid abrasive media M is then passed (along arrow F) through the hose **150** into the manifold chamber **153**, through the bores **108** and into the cylindrical chamber **135** where the fluid abrasive media M flows adjacent surfaces forming the inner diameter of the stent **10**. The media M then flows out of the bores **108** and through the central outflow opening **157** in the bottom clamp plate **156** (along arrow D).

Preferably, the fluid abrasive media M flows through the fixture **100** and past the inner diameter of the stent **10** for a desired amount of time and then the fluid abrasive media M is caused to flow in a reverse direction against the inner diameter of the stent **10**. Reversal of flow of the abrasive media M can be accomplished by removing the fixture **100** from the clamp plates **154**, **156**, reversing the fixture **100** and replacing the fixture **100** within the clamp plates **154**, **156** with the top clamp plate **154** and manifold plate **152** adjacent the bottom **104** of the fixture **100**. Alternatively, the hose **150** and a source of fluid abrasive media M can be configured to allow flow in both directions through the bores **108** of the fixture **100**.

If a streamlined contour is desired for surfaces forming the inner diameter of segments **40** (FIG. **12**) forming the stent **10**, rather than mere polishing of surfaces of the stent **10**, the fluid abrasive media M would be allowed to flow through the fixture **100** for a greater amount of time or the fluid abrasive media M could be provided with particles having a greater amount of abrasiveness. If a streamlined contour of symmetrical form is desired, the amount of time with which the media M flows in a first direction should approximate the amount that it flows in a reverse direction.

Polishing of surfaces of the stent **10** can be further enhanced by ultrasonically vibrating the abrasive media M as the abrasive media M flows through the fixture **100** and adjacent surfaces of the stent **10**. Specifically, the hose **150** and a source of fluid abrasive media M on an end of the hose **150** opposite the lower end **151** can be fitted with an ultrasonic vibration generation device which causes high frequency agitation of the fluid abrasive media M as it flows through the fixture **100**. Another parameter which can be utilized to enhance the effectiveness of the fluid abrasive media M is to supply the fluid abrasive media M at a pressure greater than atmospheric pressure as the fluid abrasive media M passes through the fixture **100**. Such enhanced pressure can be provided with pistons in communication with the fluid abrasive media M or other pumps or other pressure generation means acting on the fluid abrasive media M before or during fluid abrasive media M flow through the hose **150** and into the fixture **100**.

The fluid abrasive media M can either exit the bores **108** of the fixture **100** into an atmospheric pressure region without any specific enclosures or it can be fitted with an outlet hose similar to the hose **150** for collection of the fluid abrasive media M. If desired, the fluid abrasive media can oscillate back and forth through the bores **108** rather than flowing continuously in a first direction through the bores **108** and then being reversed in direction to flow in an opposite direction through the bores **108**.

The sizing of the bores **108** to have a similar diameter to the inner diameter of the stent **10** and the chamber **135** to have a similar diameter to the outer diameter of the stent **10**

prevents the fluid abrasive media M from flowing past surfaces forming the outer diameter of the stent **10** and maintains surfaces of the stent **10** forming the outer diameter in a substantially unpolished and unstreamlined form. It has been found to be particularly advantageous that the inner diameter of the stent **10** be polished and streamlined such that blood B or body fluids can pass through a lumen L where the stent **10** is located and radially expanded in a manner which decreases turbulence of blood B flowing through the lumen L (FIGS. **16** and **17**).

An alternative stent segment **90** is shown in FIG. **13** where only the inner diameter of the stent segment **90** has been polished and streamlined. An outer surface **92** remains substantially planar with outer edges **96** abruptly transitioning to the inner edges **98** leading to the inner surface **94** which has been streamlined. Areas of roughness R can either remain on the outer surface **92** where the stent segment **90** is located adjacent an inner surface S of the lumen L (FIGS. **16** and **17**) or be polished merely to remove roughness R but not to streamline or round off edges of the stent segment **90**. Such an alternative stent segment **90** would typically result in utilization of the stent interior polishing fixture **100** alone, with little or no utilization of the stent exterior polishing fixture **200** described below.

While various different parameters can be selected in performing the polishing process disclosed herein, it has been found effective and preferable to have abrasive media particle sizes between 0.008 and 0.0003 inches. It has been found preferable to maintain an elevated pressure between 300 and 800 pounds per square inch. An abrasive media M which has been found to be effective is aluminum oxide or silicon carbide. Alternatively, diamond particles could be utilized.

More specifically, successful tests were run of a fixture **100** similar to that disclosed herein utilizing aluminum oxide with a particle size of 0.0007 inches at a pressure of 500 pounds per square inch with a total process time of thirteen minutes (7.5 minutes each direction) and a desirable surface finish with streamlining of stainless steel stent segments **40** similar to that shown in FIGS. **12** and **15** resulted. In another test, silicon carbide was utilized with a particle size of 0.006 inches at 500 pounds per square inch with a total process time of thirteen minutes and similar contours to those shown in FIGS. **12** and **15** resulted. Specifically, surface roughness R was reduced to elimination of any prominences greater than 5 micro inches above adjacent portions of the surfaces.

Once the stents **10** have been polished by flow of the fluid abrasive media M through the fixture **100**, the hose **150** and other apparatus adjacent the fixture **100** are removed and the individual plates **120**, **140** are separated from each other for removal of the stents **10** therefrom. The cylindrical end supports **20** are then removed from the stents **10**, providing a polished stent **10'** (FIG. **18**) which is now ready for implantation and radial expansion within a body lumen L as is known in the art.

With particular reference to FIGS. **7–9**, details of the stent exterior polishing fixture **200**, which is configured to particularly provide polishing for surfaces forming an outer diameter of the stent **10**, are described in detail. The stent exterior polishing fixture **200** is shown in FIGS. **7–9** as having a void therein for supporting only a single stent **10** for polishing therein. However, the exterior polishing fixture **200** could be modified to include multiple separate voids and multiple separate plates as in the case of the interior polishing fixture **100** such that multiple stents **10** can be polished simultaneously within the stent exterior polishing fixture **200**. For convenience, the details of the stent exterior polishing fixture **200** will be described for an embodiment where only a single void for a single stent **10** is provided within the stent exterior polishing fixture **200**.

The exterior polishing fixture **200** is a solid rigid mass of material having a top **202** parallel to and spaced from a bottom **204** with sides **206** extending perpendicularly between the top **202** and the bottom **204**. Multiple slanted bores **208** pass through the top **202** and bottom **204** and communicate together such that fluid abrasive media M can flow entirely through the fixture **200** from the top **202** to the bottom **204**, in a manner similar to that described above with respect to the interior polishing fixture **100**.

The exterior polishing fixture **200** is formed from two identical end plates **210** having an outer surface **212** extending perpendicularly between a bottom **214** and a top **218** which form portions of the bottom **204** and top **202**, respectively, of the exterior polishing fixture **200**. A lateral surface **216** defines surfaces of the end plate **210** perpendicular to the bottom **214** and top **218** and also perpendicular to the outer surface **212**.

A cylindrical recess **220** somewhat analogous to the cylindrical chamber **135** in the interior polishing fixture **100** is located within the exterior polishing fixture **200** in fluid communication with the slanted bores **208**. The cylindrical recess **220** is formed between the two end plates **210** such that the cylindrical recess **220** is in fact formed in an inner surface **230** parallel to and spaced from the outer surfaces **212** of the two end plates **210**. Each inner surface **230** includes a flat plane **232** defining portions of the inner surface **230** where the cylindrical recess **220** is not located and a cylindrical recess wall **234** defining exactly one-half of the cylindrical recess **220**. The cylindrical recess wall **234** is preferably semi-cylindrical in form and has a diameter greater than an outer diameter of the stent **10**.

A top blind bore **240** extends up from the cylindrical recess **220** between the multiple slanted bores **208**. The top blind bore **240** extends up to a top bore wall **242** perpendicular to the cylindrical recess wall **234** of the cylindrical recess **220**. A bottom blind bore **250** similar to the top blind bore **240** but below the bottom of the cylindrical recess **220** is also located within the exterior polishing fixture **200**. The bottom blind bore **250** includes a bottom bore wall **252** parallel to the top bore wall **242**.

Between the top bore wall **242** and bottom bore wall **252** and the cylindrical recess wall **234** two similar collar support regions **260** are located. The top blind bore **240**, bottom blind bore **250** and two collar support regions **260** are each cylindrical in form but exhibit different diameters extending away from a central axis common with the cylindrical recess **220**. A recess edge **262** defines a diameter transition between the cylindrical recess wall **234** and the two collar support regions **260**. A bore edge **264** is located at a transition between the collar support regions **260** and the two blind bores **240**, **250**.

Preferably, the slanted bores **208** extend from the top **202** and the bottom **204** up into the collar support regions **260**. Preferably, two slanted bores **208** are located within each end plate **210** such that a total of four slanted bores **208** pass from the top **202** into the cylindrical recess **220** and four slanted bores **208** pass from the bottom **204** into the cylindrical recess **220**.

The cylindrical recess wall **234** has a diameter greater than an outer diameter of the stent **10**. The collar support regions **260** have a diameter similar to an outer diameter of the stent **10**. The blind bores **240**, **250** have a diameter similar to an inner diameter of the stent **10**.

A shaft **270** is provided having a length similar to a distance between the top bore wall **242** and the bottom bore wall **252** and having a diameter similar to a diameter of the blind bores **240**, **250** and the inner diameter of the stent **10**. Thus, the stent **10** can be placed on the shaft **270** with the inner diameter of the stent **10** adjacent the shaft **270**. The shaft **270** includes a top end **272** parallel to and spaced from a bottom end **274** with a cylindrical surface **276** sized to be located adjacent the inner diameter of the stent **10**. The shaft **270** is located within the exterior polishing fixture **200** with the top end **272** within the top blind bore **240** and the bottom end **274** within the bottom blind bore **250** when the exterior polishing fixture **200** is in use for polishing exterior surfaces of the stent **10**.

An upper collar **280** is provided having an inner surface **282** with a diameter similar to a diameter of the cylindrical surface **276** of the shaft **270**. The upper collar **280** includes an outer surface **284** with a diameter similar to a diameter of the collar support regions **260** and the outer diameter of the stent **10**. The upper collar **280** is a hollow cylindrical rigid construct extending from a circular top edge **286** to a circular bottom edge **288**. The upper collar **288** has a length between the top edge **286** and the bottom edge **288** which causes the upper collar **280** to be longer than a distance within each collar support region **260** from the recess edge **262** to the bore edge **264**. Thus, when the upper collar **280** is located on the shaft **270** within the fixture **200** the upper collar **280** extends down into the cylindrical recess **220** somewhat. A lower collar **290** is provided with a form similar to that of the upper collar **280**.

Preferably, the cylindrical recess **220** has a length between the recess edges **262** which is slightly greater than a length of the stent **10** and actually includes a length of the stent **10** and a length of portions of each collar **280**, **290** which extend from the recess edges **262** into the cylindrical recess **220**. Thus, when the shaft **270** is located within the exterior polishing fixture **200** with the top end **272** within the top blind bore **240** and the bottom end **274** within the bottom blind bore **250** and with the collars **280**, **290** located upon the shaft **270** and within the collar support regions **260** (as shown in FIG. **7**), sufficient space is provided between the upper collar **280** and the lower collar **290** for the stent **10** to be placed over the shaft **270** and between the upper collar **280** and the lower collar **290** without any axial motion of the stent **10** between the collars **280**, **290** within the exterior polishing fixture **200** allowed.

Preferably, the shaft **270**, upper collar **280** and lower collar **290** are each separate pieces so that the stent **10** can be easily placed upon the shaft **270** with the collars **280**, **290** also on the shaft **270** adjacent ends of the stent **10**. The shaft **270**, collars **280**, **290** and stent **10** can then be simultaneously placed together within the cylindrical recess **220**, top blind bore **240**, bottom blind bore **250** and collar support regions **260** as the two end plates **210** of the exterior polishing fixture **200** are closed together.

Preferably, closure bolts similar to the closure bolts **212** of the interior polishing fixture **100** are utilized to secure the end plates **210** together. Also, a clamping system, manifold plate and hose are provided in a manner similar to that discussed above with respect to the interior polishing fixture **100** to deliver fluid abrasive media M through the slanted bores **208** and into the cylindrical recess **220**.

Because the cylindrical recess **220** has a diameter greater than the outer diameter of the stent **10**, and because the shaft **270** prevents fluid abrasive media M from flowing adjacent interior surfaces of the stent **10**, the fluid abrasive media M is caused to flow exclusively over surfaces of the stent **10** forming the outer diameter of the stent **10**. As with the use of the interior polishing fixture **100** discussed above, various different fluid abrasive media M can be utilized with different pressures, durations, particle sizes, and ultrasonic vibration, as required to produce a desired finished surface for outer surfaces of the stent **10**. Preferably, the outer diameter of the stent **10** is polished to have a smooth surface but is not significantly streamlined. Rather the stent segments **40** are provided with relatively abrupt leading and trailing edges **50**, **52** (FIGS. **12** and **15**) so that the stent **10** will remain securely in place when radially expanded within a body lumen L, without sliding along the inner surface S of the body lumen L, but preferably does not have patches of roughness R (FIGS. **13** and **14**) which might cause irritation of the body lumen L and lead to thrombus, restenosis or other detrimental complications.

Preferably, the slanted bores **208** enter into the cylindrical recess **220** at a location where the upper collar **280** and lower collar **290** are provided. Thus, extreme upper portions of the cylindrical recess **220** provide a zone where the fluid abrasive media M can flow laterally between adjacent slanted bores **208** and fill the cylindrical recess **220** before the fluid abrasive media M flows down to the cylindrical recess **220** and comes into contact with surfaces of the stent **10** forming the outer diameter of the stent **10**. In this way, all locations within the cylindrical recess **220** are provided with fluid abrasive media M for polishing, without any vacant regions in the abrasive media M flow.

While the exterior polishing fixture **200** has been separately disclosed and described with respect to a preferred interior polishing fixture **100**, it is understood that a fixture could be provided which allows abrasive media M to flow simultaneously adjacent an inner diameter and an outer diameter of the stent **10** such that a single composite fixture rather than two separate fixtures would be provided. The benefits of such a composite fixture, including overall simplification of the stent polishing process would necessarily be compared with the added complexity of such a fixture and difficulties associated with securing the stent **10** in position within such a fixture and adequately supporting the stent **10** such that the stent **10** is not damaged during high pressure flow of the abrasive media M adjacent surfaces of the stent **10**.

Other further modifications to the fixtures **100**, **200** and the polishing process could also be resorted to without departing from the scope of the invention. The specific embodiments disclosed herein are provided merely by way of example and to provide a best mode and preferred embodiment for practicing this invention and should not be considered as further limiting the claims included herein below.

What is claimed is:

1. A method for polishing surfaces of a cylindrical radially expandable surgical stent including the steps of:

selecting an abrasiveness for particles within a fluid abrasive media;

providing a source of the fluid abrasive media;

orienting the radially expandable surgical stent with a central axis thereof extending in an axial direction;

flowing the abrasive media past the radially expandable surgical stent in an axial direction with the abrasive media coming into physical contact with the surfaces of the radially expandable surgical stent; and

wherein said flowing step includes the further step of limiting the abrasive media to physical contact with

inner surfaces and side surfaces of the cylindrical radially expandable surgical stent, such that only the side surfaces and the inner surfaces of the radially expandable surgical stent facing the central axis of the stent are polished by the abrasive media flowing adjacent the stent.

2. The stent polishing method of claim 1 including the further step of locating the radially expandable surgical stent within a rigid fixture having at least one hole passing through the fixture, the hole located in fluid communication with the source of fluid abrasive media, the hole including a cylindrical chamber therein, the cylindrical chamber having a diameter similar to an outer diameter of the cylindrical radially expandable surgical stent and a length similar to a length of the stent, the stent located within the cylindrical chamber during said flowing step.

3. A method for polishing surfaces of a cylindrical radially expandable surgical stent including the steps of:

selecting an abrasiveness for particles within a fluid abrasive media;

providing a source of the fluid abrasive media;

orienting the radially expandable surgical stent with a central axis thereof extending in an axial direction;

flowing the abrasive media past the radially expandable surgical stent in an axial direction with the abrasive media coming into physical contact with the surfaces of the radially expandable surgical stent; and

wherein said flowing step includes the further step of limiting the abrasive media to physical contact with outer surfaces and side surfaces of the radially expandable surgical stent, such that only the side surfaces and the outer surfaces of the radially expandable surgical stent facing away from the central axis of the stent are placed in contact with the abrasive media flowing adjacent the stent.

4. The stent polishing method of claim 3 including the further step of locating the radially expandable surgical stent within an exterior polishing fixture formed of rigid material having at least one hole passing through the fixture, the hole located adjacent the source of fluid abrasive media in an orientation allowing the fluid abrasive media to pass through the hole, the hole including a cylindrical recess therein, the cylindrical recess having a diameter greater than an outer diameter of the cylindrical radially expandable surgical stent, the cylindrical recess including a shaft centrally located therein with a long axis thereof colinear with a long axis of the cylindrical recess, the shaft having a width similar to an inner diameter of the cylindrical radially expandable surgical stent, the cylindrical recess having a length similar to a length of the radially expandable surgical stent, the stent located within the recess with the shaft passing axially through the stent during said flowing step.

5. A method for polishing surfaces of a cylindrical radially expandable surgical stent including the steps of:

selecting an abrasiveness for particles within a fluid abrasive media;

providing a source of the fluid abrasive media;

orienting the radially expandable surgical stent with a central axis thereof extending in an axial direction;

flowing the abrasive media past the radially expandable surgical stent in an axial direction with the abrasive media coming into physical contact with the surfaces of the radially expandable surgical stent;

vibrating the abrasive media ultrasonically as the abrasive media flows past the radially expandable surgical stent during said flowing step; and

pressurizing the abrasive media to a pressure above atmospheric pressure while the abrasive media flows past the radially expandable surgical stent during said flowing step.

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